(23)

No. 05-608

FILED
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SUPREME COURT, U.S.

IN THE

Supreme Court of the United States

MEDIMMUNE, INC.,
Petitioner,

v.

GENENTECH, INC., *et al.*,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

JOINT APPENDIX
VOLUME I

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NOTICE

The following items have been omitted in printing this appendix because they appear in the following pages of the printed appendix to the petition for certiorari. They are incorporated herein by reference:

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Certificates of service whenever appended to documents appearing herein have been omitted in printing. Where redactions have been made, they are noted by ellipses or otherwise.

U.S. DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
(Western Division - Los Angeles)

CIVIL DOCKET FOR CASE #: 2:03-cv-02567-MRP-CT

MEDIMMUNE INC.,

Plaintiff,

v.

GENENTECH INC., *et al.*,

Defendants.

Assigned to: Judge Mariana R. Pfaelzer
Referred to: Discovery Carolyn Turchin
Demand: $0
Cause: 28:1338 Patent Infringement
Date Filed: 04/11/2003
Jury Demand: Both
Nature of Suit: 830 Patent
Jurisdiction: Federal Question

DATE	NO.	PROCEEDINGS
		* * * *
04/11/2003	1	COMPLAINT filed Summons(es) 20 days issued referred to Discovery Carolyn Turchin (rrey) (Entered: 04/14/2003)
		* * * *
05/29/2003	16	ORDER TRANSFERRING ACTION Under Section 3.1 of General Order 224 Case transferred from Judge Terry J. Hatter to Judge Mariana R. Pfaelzer for all further proceedings. The case number will now reflect the initials of the transferee Judge [CV 03-3567 MRP (CTx)] (cc: all counsel) (m) (Entered: 05/29/2003)

DATE	NO.	PROCEEDINGS
		* * * *
06/04/2003	20	ANSWER filed by defendant Celltech R&D Ltd to complaint [1-1]; jury demand (el) (Entered: 06/05/2003)
06/04/2003	21	NOTICE OF MOTION AND MOTION by defendant Genentech Inc to dismiss the third and eleventh causes of action ; motion hearing set for 10:00 7/21/03; Memorandum of Points and Authorities in support (el) (Entered: 06/05/2003)
06/04/2003	22	NOTICE OF MOTION AND MOTION by defendant City of Hope Natl for joinder in motion to dismiss the third cause of action [21-1] ; motion hearing set for 10:00 7/21/03 (el) (Entered: 06/05/2003)
		* * * *
6/05/2003	24	NOTICE OF ERRATA by defendant Genentech Inc correcting motion to dismiss the third and eleventh causes of action [21-1], filed on 6/4/03 (el) (Entered: 06/06/2003)
		* * * *
06/23/2003	32	STIPULATION and ORDER by Judge Mariana R. Pfaelzer that the hearing on motion to dismiss the third and eleventh causes of action [21-1] shall be continued to 10:00 7/21/03; any opposition to the Motion to dismiss shall be filed 21 days before the hearing date. Any reply in support shall be filed seven (7) days before the hearing date (el) (Entered: 06/25/2003)

DATE	NO.	PROCEEDINGS
07/14/2003	33	OPPOSITION by plaintiff Medimmune Inc to motion to dismiss the third and eleventh causes of action [21-1] (el) (Entered: 07/15/2003)
		* * * *
07/28/2003	35	REPLY MEMORDUM OF POINTS AND AUTHORITIES by defendant Genentech Inc insupport of motion to dismiss the third and eleventh causes of action [21-1] (el) (Entered: 07/29/2003)
07/28/2003	36	REQUEST by defendant Genentech Inc for Judicial Notice re motion to dismiss the third and eleventh causes of action [21-1]; Lodged proposed order (el) (Entered: 07/29/2003)
07/28/2003	37	DECLARATION of Susan L Friedman in support by defendant Genentech Inc of request for judicial notice in support of reply memorandum for motion to dismiss the third and eleventh causes of action [21-1] (el) (Entered: 07/29/2003)
		* * * *
08/04/2003	39	MINUTES before Judge Mariana R. Pfaelzer: Defendant's motion to dismiss the third and eleventh causes of action [21-1]; joined by City of Hope [21-1] [22-1]. Court GRANTS the motion to dismiss as to the 3rd cause of action with leave until 08/13/03, to amend. Court GRANTS the motion to dismiss as to the 11th cause of action without leave to amend. The parties shall submit their Rule 26() Report no later

DATE	NO.	PROCEEDINGS
		than 08/08/03, and shall give notice of a hearing date and time for the Rule 26(f) scheduling conference in the report. CR: Lisa Gonzales (jp) (Entered: 08/04/2003)
08/08/2003	40	JOINT RULE 26 DISCOVERY PLAN filed; est length of trial 3-6 weeks (el) (Entered: 08/11/2003)
08/11/2003	41	ORDER by Judge Mariana R. Pfaelzer that the motion to dismiss the third and eleventh causes of action [21-1] is GRANTED as to the Third Cause of action, and plaintiff MedImmune has until 8/13/03 to file and serve a First Amended Complaint. The motion is GRANTED as to the Eleventh cause of action without leave to amend. (el) (Entered: 08/12/2003)
08/13/2003	42	FIRST AMENDED COMPLAINT [1-1] by plaintiff Medimmune Inc; jury demand. Summons not issued (el) (Entered: 08/14/2003)
08/22/2003	43	RECEIPT OF TRANSCRIPT of proceedings for the following date(s): 08/04/03 (Re:), CR: Lisa M. Gonzalez. (wdc) (Entered: 08/25/2003)
		* * * *
09/02/2003	44	ANSWER filed by defendant Celltech R&D Ltd to First amended complaint [42-1], jury demand (el) (Entered: 09/03/2003)
09/02/2003	45	ANSWER filed by defendant City of Hope National Medical Center's to First amended complaint [42-1]; jury demand (el) (Entered: 09/04/2003)

DATE	NO.	PROCEEDINGS
09/02/2003	46	ANSWER filed by defendant Genentech Inc to First amended complaint [42-1]; jury demand (el) (Entered: 09/04/2003)
09/02/2003	47	SCHEDULING CONFERENCE STATEMENT by defendant Genentech Inc in accordance with the parties' agreement and athe Joint Rule 26(f) Report [40-1]; addressing bifurcation issues in advance of the 9/8/03 Scheduling Conference (el) (Entered: 09/04/2003)
09/02/2003	48	SUBMISSION regarding Bifurcation and Scheduling by defendant Celltech R&D Ltd (el) (Entered: 09/04/2003)
09/02/2003	49	MEMORANDUM IN SUPPORT OF ITS PROPOSED DISCOVERY SCHEDULE AND IN OPPOSITION to defendants' requests to bifurcate or stay discovery on "Antitrust" issues by plaintiff Medimmune Inc (el) (Entered: 09/04/2003)
09/02/2003	50	DECLARATION of Jeffrey R Witham in support of plaintiff Medimmune Inc's proposed discovery schedule and in Opposition to defendants' requests to bifurcate or stay discovery on "Antitrust" issues (el) (Entered: 09/04/2003)
09/08/2003	51	MINUTES: Scheduling/Status Conference hearing held. Court and counsel schedule a telephone conference call for Monday, 12:00 9/15/03 , with Mr Kurzwiel, plaintiffs' counsel, arranging this call. Counsel are instructed to prepare a revised stipulated schedule confirming the pretrial and trial

DATE	NO.	PROCEEDINGS
		dates by Judge Mariana R. Pfaelzer CR: Margaret Babykin (el) (Entered: 09/16/2003)
09/15/2003	53	MINUTES: Conference call held . Court will issue a scheduling order a a later date by Judge Mariana R. Pfaelzer CR: None Present (pj) (Entered: 09/17/2003)
09/16/2003	52	SCHEDULING ORDER: The parties adhere to the following scheduling order by Judge Mariana R. Pfaelzer (pj) (Entered: 09/17/2003)
09/22/2003	54	AMENDED ANSWER [44-1] by defendant Celltech R&D Ltd to First Amended Complaint; jury demand (el) (Entered: 09/23/2003)
09/30/2003	55	NOTICE OF MOTION AND MOTION by defendant Celltech R&D Ltd for judgment on the pleadings ; motion hearing set for 10:00 10/20/03 (el) (Entered: 10/01/2003)
09/30/2003	56	NOTICE OF motion for judgment on the pleadings [55-1] filed by defendant Celltech R&D Ltd (el) (Entered: 10/01/2003)
09/30/2003	57	REQUEST by defendant Celltech R&D Ltd for Judicial Notice re motion for judgment on the pleadings [55-1] (el) (Entered: 10/01/2003)
09/30/2003	58	DECLARATION of Jason A Carotty in support by defendant Celltech R&D Ltd of motion for judgment on the pleadings [55-1] (el) (Entered: 10/01/2003)

DATE	NO.	PROCEEDINGS
10/06/2003	59	STIPULATION and ORDER by Judge Mariana R. Pfaelzer that the hearing on motion for judgment on the pleadings [55-1], presently scheduled for 10/20/03 shall be continued to 10:00 11/10/03; and any opposition to the Motion for Judgment on the Pleadings shall be served and filed twenty-one (21) days before the hearing date. Reply shall be served and filed seven (7) days before the hearing (el) (Entered: 10/07/2003)
10/16/2003	60	EX PARTE APPLICATION filed by defendant Genentech Inc for case management conference related to NOERR motions Lodged order (el) (Entered: 10/20/2003)
10/16/2003	61	DECLARATION of Daniel M Wall by defendant Genentech Inc of ex parte application for case management conference related to NOERR motions [60-1] (el) (Entered: 10/20/2003)
10/16/2003	62	EX PARTE APPLICATION filed by plaintiff Medimmune Inc for an order consolidating the briefing schedule and hearings on defendnants' [*sic*] motion for judgment on the pleadings and motion for summary judgment . Declaration of Jeffrey R Witham; Lodged Order (el) (Entered: 10/20/2003)
10/16/2003	63	DECLARATION of Jeffrey R Witham in support by plaintiff Medimmune Inc of ex parte application for an order consolidating the briefing schedule and hearings on

DATE	NO.	PROCEEDINGS
		defendants' motion for judgment on the pleadings and motion for summary judgment [62-1] (el) (Entered: 10/20/2003)
10/17/2003	64	RESPONSE by defendant Celltech R&D Ltd to ex parte application for an order consolidating the briefing and hearings on defendnants' [*sic*] motion for judgment on the pleadings and motion for summary judgment [62-1], and ex parte application by Genentech's case management conference related to NOERR motions [60-1] (el) (Entered: 10/20/2003)
10/17/2003	65	DECLARATION of Charles S Barquist in support by defendant Celltech R&D Ltd of response to ex parte applications by Medimmune Inc for an order consolidating the briefing schedule and hearings on defendants' motion for judgment on the pleadings and for summary judgment [62-1] and Genentech Inc's ex parte application for case management conference related to NOERR motions [60-1] (el) (Entered: 10/20/2003)
10/17/2003	66	MINUTES: (IN CHAMBERS) In chambers and offs [*sic*] the record, a conference call is held. Court and counsel discuss the status of the case, Genentech's Ex Parte for a Case Management Conference is now moot. Court instructs counsel as to Medimmune's Ex Parte Request if in need of further action by the court, they are to contact the Clerk to Judge Pfaelzer by Monday, 10/10/03. Off the record counsel orally stipulate they have

DATE	NO.	PROCEEDINGS
		come to an agreement as to Medimmune's Ex Parte Request. Medimmune's Ex Parte Request for an order consolidating the briefing schedule and hearings on defendnants' [*sic*] motion for judgment on the pleadings and motion for summary judgment [62-1] is now moot. by Judge Mariana R. Pfaelzer CR: None Present (el) (Entered: 10/21/2003)
10/21/2003	67	MINUTES: (IN CHAMBERS) The parties' request for a stipulated protective order has been referred to the magistrate judge and is DENIED WITHOUT PREJUDICE. The Court declines to sign the overboard protective order (see document for details) by Judge Mariana R. Pfaelzer (el) (Entered: 10/22/2003)
10/23/2003	68	STIPULATION and ORDER by Judge Mariana R. Pfaelzer Defendant Genentech Inc shall file and serve its motion for summary judgment on October 31, 2003. Plaintiff medimmune Inc shall file and serve a combined opposition to GEnentech Inc's motion for summary judgment and Celltech R&D Ltd's motion for judgment on the pleadings on November 17, 2003. Defendant Genentech Inc shall file and serve its reply brief in support of its motion for summary judgment on December 5, 2003. Defendant Celltech R&D Ltd shall file and serve its reply brief in support of its motion for judgment on the pleadings on December 5, 2003. The Court shall hear argument on Genetech Inc's motion for summary judg-

DATE	NO.	PROCEEDINGS
		ment and Celltech R&D motion for judgment on the pleadings at 10:00am on December 15, 2003. There will be no further continuance of the briefing schedule or the hearing on Celltech R&D Ltd's motion for judgment on the pleadings [55-1] (pj) (Entered: 10/27/2003)
10/31/2003	69	NOTICE OF MOTION AND MOTION by defendant Genentech Inc for summary judgment on plaintiffs antitrust claims ; motion hearing on 12/15/03 at 10:00 a.m.; Memorandum in support; Lodged proposed statement (el) (Entered: 11/03/2003)
10/31/2003	70	MEMORANDUM IN SUPPORT by defendant Genentech Inc of motion for summary judgment on plaintiffs antitrust claims [69-1] (el) (Entered: 11/03/2003)
10/31/2003	71	NOTICE OF APPLICATION AND APPLICATION filed by defendant Genentech Inc for leave to file under seal certain exhibits to declaration of Vernon M Winters ; Memorandum of Points and Authorities in support. Lodged proposed order and exhibit Nos. 13 and 14 (el) (Entered: 11/03/2003)
10/31/2003	72	DECLARATION of Timothy R Schwartz in support by defendant Genentech Inc re application for leave to file under seal certain exhibits to declaration of Vernon M Winters [71-1] (el) (Entered: 11/03/2003)

DATE	NO.	PROCEEDINGS
10/31/2003	73	DECLARATION of Christopher S Yates in support by defendant Genentech Inc re application for leave to file under seal certain exhibits to declaration of Vernon M Winters [71-1] (el) (Entered: 11/03/2003)
10/31/2003	74	DECLARATION of Sharon E Crane Ph.D. by defendant Genentech Inc re application for leave to file under seal certain exhibits to declaration of Vernon M Winters [71-1] (el) (Entered: 11/03/2003)
10/31/2003	75	DECLARATION of Vernon M Winters by defendant Genentech Inc in support of application for leave to file under seal certain exhibits to declaration of Vernon M Winters [71-1] (el) (Entered: 11/03/2003)
		* * * *
11/04/2003	77	JOINDER by defendant Celltech R&D Ltd joining application for leave to file under seal certain exhibits to of Vernon M Winters [71-1] (el) (Entered: 11/05/2003)
11/07/2003	79	ORDER by Judge Mariana R. Pfaelzer that Genentech's application for leave to file under seal certain exhibits to declaration of Vernon M Winters [71-1] is GRANTED as follows: 1. The non-redacted version of the Declaration of Vernon M Winters that was lodged confidentially under seal with the Court 10/31/03 shall be filed under seal. 2. No persons other than the Court and counsel of record are authorized to inspect the above-listed records (see document for list) filed under seal. (el) (Entered: 11/07/2003)

DATE	NO.	PROCEEDINGS
11/07/2003	80	JOINT CLAIM CONSTRUCTION STATEMENT by plaintiff and defendants (el) (Entered: 11/10/2003)
11/10/2003	85	ORDER by Judge Mariana R. Pfaelzer that plaintiff Medimmune Inc's application for leave to file under seal its opposition, Statement of Genuine Issues, supporting declaration of aldo Badini and exhibits to Hunter declaration of Tanya Hunter [83-1] is GRANTED. (el) (Entered: 11/21/2003)
11/17/2003	81	MEMORANDUM OF POINTS SNA AUTHORITIES filed by plaintiff Medimmune Inc in opposition to defendant Celltech R&D's motion for judgment on the pleadings [55-1], and defendant Genentech Inc's motion for summary judgment on plaintiffs antitrust claims [69-1] (el) (Entered: 11/18/2003)
11/17/2003	82	STATEMENT OF GENUINE ISSUES OF MATERIAL FACT and reponses to proposed conclusions of law in opposition by plaintiff Medimmune Inc to Genentech Inc's motion for summary judgment on plaintiffs antitrust claims [69-1] (el) (Entered: 11/18/2003)
11/17/2003	83	APPLICATION filed by plaintiff Medimmune Inc for leave to file under seal its opposition, Statement of Genuine Issues, supporting declaration of aldo Badini and exhibits to Hunter declaration Memorandum of Points and Authorities in support; Declaration of Tanya Hunter Lodged Ord (el) (Entered: 11/18/2003)

DATE	NO.	PROCEEDINGS
		* * * *
11/17/2003	87	DECLARATION of Tanya Hunter in support by plaintiff Medimmune Inc of denial or continuance of summary judgment under FRCP 56(F) [69-1] (el) (Entered: 11/24/2003)
11/17/2003	88	DECLARATION of Aldo A Badini in support of plaintiff Medimmune Inc's request for denial or continuance of motion for summary judgment on antitrust claims [69-1] (el) (Entered: 11/24/2003)
11/17/2003	89	DECLARATION of Harvey Kurzweil in support by plaintiff Medimmune Inc's request for denial or continuance of motion for summary judgment on antitrust claims [69-1] (el) (Entered: 11/24/2003)
11/24/2003	93	JOINT NOTICE OF MOTION AND MOTION for protective order ; Declarations of-William Bertrand, John Slater, Timothy Schwartz and Gordon A Goldsmith in support thereof (shb) (Entered: 11/25/2003)
11/24/2003	94	JOINDER by defendant Celltech R&D Ltd joining Medimmune's application for leave to file certain documents under seal; Declaration of John A.D. Slater; Lodged proposed order (shb) (Entered: 11/25/2003)
12/03/2003	95	ORDER by Judge Mariana R. Pfaelzer It is therefor ordered that Medimmune's application for leave to file under sela is GRANTED IN PART. The non-redacated versions of Medimmune's opposition, Statement, Declaration, and Exhibits lodged

DATE	NO.	PROCEEDINGS
		under seal shall be filed under seal [93-1] (pj) (Entered: 12/05/2003)
12/05/2003	96	APPLICATION filed by defendant Celltech R&D Ltd for leave to file its reply brief under seal ; Lodged order and sealed reply brief (el) (Entered: 12/09/2003)
12/05/2003	97	REPLY BRIEF by defendant Celltech R&D Ltd in support of its motion for judgment on the pleadings [55-1] (el) (Entered: 12/09/2003)
		* * * *
12/05/2003	99	APPLICATION filed by defendant Genentech Inc for leave to file under seal a portion of Genentech Inc's reply memorandum in support of motion for summary judgment on plaintiffs antitrust claims ; Memorandum of Points and Authorities in support; Lodged prop ord prop under seal document (el) (Entered: 12/09/2003)
12/05/2003	100	REPLY MEMORANDUM by defendant Genentech Inc in support of motion for summary judgment on plaintiffs antitrust claims [69-1] (el) (Entered: 12/09/2003)
12/05/2003	101	SUPPLEMENT by defendant Genentech Inc re declaration of CHRISTOPHER S YATES [73-1] (el) (Entered: 12/09/2003)
		* * * *
12/08/2003	103	ORDER by Judge Mariana R. Pfaelzer that Celltech's application for leave to file its reply brief under seal [96-1], is GRANTED. (el) (Entered: 12/17/2003)

DATE	NO.	PROCEEDINGS
12/08/2003	105	ORDER by Judge Mariana R. Pfaelzer granting application for leave to file under seal a portion of Genentech Inc's reply memorandum in support of motion for summary judgment on plaintiffs antitrust claims [99-1] (el) (Entered: 12/17/2003)
12/08/2003	107	JOINT STIPULATION REGARDING ENTRY OF STIPULATED PROTECTIVE ORDER and ORDER by Judge Mariana R. Pfaelzer that the parties must follow Local Rule 79-5 for making applications to the Court for filing documents under seal. (el) (Entered: 12/17/2003)
12/08/2003	108	STIPULATED PROTECTIVE ORDER by Judge Mariana R. Pfaelzer that this Protective Order shall apply to all information, documents and other items subject to discovery in this action, including without limitation testimony adduce at depositions upon oral examination or upon written questions pursuant to Rules 30 and 31, etc (see document for specifics) (el) (Entered: 12/17/2003)
12/15/2003	110	MINUTES: Counsel present, hearing held. Oral argument heard, Court takes the motion for judgment on the pleadings [55-1] and motion for summary judgment on plaintiffs antitrust claims [69-1], under submission and will issue an order at a later date submitted by Judge Mariana R. Pfaelzer CR: Margaret Babykin (el) (Entered: 12/24/2003)

DATE	NO.	PROCEEDINGS
12/22/2003	109	JOINDER by defendant City of Hope Nati joining opening brief regarding claim construction. (bp) (Entered: 12/23/2003)
12/22/2003	113	OPENING BRIEF REGARDING CLAIM CONSTRUCTION FILED by defendant Genentech Inc (el) (Entered: 12/24/2003)
12/22/2003	114	DECLARATION of Dean G Dunlavey in support by defendant Genentech Inc's opening brief [113-1] (el) (Entered: 12/24/2003)
12/23/2003	111	MEMORANDUM OF DECISION AND ORDER by Judge Mariana R. Pfaelzer that summary judgment on plaintiffs antitrust claims [69-1], and related state causes of action is GRANTED in favor of the Defendants with respect to the fifth, sixth, eighth, ninth and tenth causes of action in the First Amended Complaint [55-1]. (see document for specifics) (el) (Entered: 12/24/2003)
12/23/2003	112	NOTICE OF DISCREPANCY AND ORDER by Judge Mariana R. Pfaelzer ordering Opening brief, Declaration in support submitted by defendant Genentech Inc received on 12/22/03 to be fld and processed; fld date to be the date the doc was stamped "received but not fld" w/the Clerk (el) (Entered: 12/24/2003)
12/29/2003	115	EX PARTE APPLICATION filed by plaintiff Medimmune Inc for an order extending deadline to file a motion to amend the pleadings Lodged Prop ord (el) (Entered: 12/30/2003)

DATE	NO.	PROCEEDINGS
12/29/2003	116	DECLARATION of Jeffrey R Witham in support by plaintiff Medimmune Inc re ex parte application extending deadline file a motion to amend the pleadings [115-1] and re notice to other parties (el) (Entered: 12/30/2003)
12/30/2003	117	MINUTES: (IN CHAMBERS) the Court is in receipt of Plaintiffs ex parte application extending deadline to file a motion to amend the pleadings [115-1]. The Court now extends the deadline to file a motion to amend the pleadings from 12/29/03 to 1/12/04. No further continuances will be granted by Judge Mariana R. Pfaelzer CR: None Present (el) (Entered: 2/31/2003)
12/30/2003	118	OPPOSITION by defendant Genentech Inc t [*sic*] Medimmune'so [*sic*] ex parte application for an order extending the deadline to file a motion to amend the pleadings [115-1] (jp) (Entered: 12/31/2003)
12/30/2003	119	OPPOSITION by defendant Celltech R&D Ltd to Medimmune's ex parte application for an order extending the deadline to file a motion to amend the pleadings [115-1] (jp) (Entered: 12/31/2003)
01/14/2004	120	AMENDED MEMORANDUM OF DECISION and Order by Judge Mariana R. Pfaelzer regarding Defendant Genentech's Motion for Summary Judgment[69], and Defendant Celltech's Motion for Judgment on the Pleadings[55]. Based upon the fact that Noerr-Pennington immunity bars Med-

DATE	NO.	PROCEEDINGS
		Immune's failure to adequately plead any antitrust violation (such as price-fixing in the ARLA) that is not barred by Noerr-Pennington, summary judgment for the Defendants is hereby GRANTED with respect to the fifth, sixth, seventh, eighth, ninth, and tenth causes of action in the First Amended Complaint (see document for details) (el,) (Entered: 01/15/2004)
01/16/2004	123	OPPOSITION filed by Defendant Genentech Inc to Medimmune's MOTION for Leave to File a Second Amended Complaint [121] (el,) (Entered: 01/22/2004)
01/16/2004	124	OPPOSITION filed by Defendant Celltech R&D Ltd to Medimmune's MOTION for Leave to File Second Amended Complaint [121] . (el,) (Entered: 01/22/2004)
01/16/2004	125	DECLARATION of Steven M Haines in opposition to MOTION for Leave to File a Second Amended Complaint [121] filed by Defendant Celltech R&D Ltd. (el,) (Entered: 01/22/2004)
		* * * *
01/20/2004	127	NOTICE OF MOTION AND MOTION for Entry of Final Judgment filed by Defendant Celltech R&D Ltd. Motion set for hearing on 2/9/2004 at 10:00 AM before Honorable Mariana R. Pfaelzer. (el,) (Entered: 01/22/2004)

DATE	NO.	PROCEEDINGS
01/20/2004	128	NOTICE OF MOTION re MOTION for Entry of Final Judgment[127] filed by Defendant Celltech R&D Ltd. (el,) (Entered: 01/22/2004)
		* * * *
01/21/2004	129	MINUTES In Chambers Conference held before Judge Mariana R. Pfaelzer : The Court, on its own Motion, continues MOTION for Leave to File Second Amended Complaint [121] and Markman Hearing regarding Claim Construction continued to 2/23/2004 at 10:00 AM before Honorable Mariana R. Pfaelzer. Court Reporter: Not Present. (el,) (Entered: 01/22/2004)
01/22/2004	139	JOINT STIPULATION Regarding MOTION to Compel Defendant Genentech Inc.'s Responses to First Set of Request for Production of Documents and Interrogatories[138] filed by plaintiff Medimmune Inc. (yl,) (Entered: 02/05/2004)
01/26/2004	134	OPPOSITION BRIEF regarding Claim Construction filed by Plaintiff Medimmune Inc. (el,) (Entered: 01/29/2004)
01/26/2004	135	DECLARATION of Jeffrey R Witham in support of Plaintiff Medimmune Inc's Opposition Brief in support of claim construction [134] filed by Plaintiff Medimmune Inc. (el,) (Entered: 01/29/2004)

DATE	NO.	PROCEEDINGS
01/27/2004	131	NOTICE OF DISCREPANCY AND ORDER: by Judge Carolyn Turchin, This motion should be filed before Judge Pfaelzer. According to the Judges' Procedures and Schedules on the Court's website, discovery motions are to be scheduled before the District Judge and may, but not necessarily, be referred to the magistrate judge on a motion by motion basis. (dam) (Entered: 01/28/2004)
01/28/2004	132	STIPULATION AND ORDER by Judge Mariana R. Pfaelzer : That 1. The hearing on Celltech's MOTION for Entry of Final Judgment[127] shall be continued for hearing on 2/23/2004 at 10:00 AM before Honorable Mariana R Pfaelzer. 2. Opposition or other response shall be filed and served on or before 2/6/04; 3. Any reply in support of Celltech's motion shall be filed and served by Celltech on or before 2/13/04; 4. Any reply in support of MedImmune's Motion for leave to file a second amended complaint shall be served and filed by MediMMune on or before 2/13/04; and 5. Any reply to Medimmune's opposition brief in support of Claim Construction shall be served and filed by Genentech and/or City of Hope on or before 2/13/04.(el,) Modified on 1/30/2004 (el,). (Entered: 01/29/2004)

DATE	NO.	PROCEEDINGS
01/28/2004	133	ORDER by Judge Mariana R. Pfaelzer regarding Terms to be construed at Markman hearing. That the parties are instructed to meet and confer to reduce the number of Markman claims. No later than Monday, 2/9/04, the parties will file a joint submission of the terms to be decided in the 2/23/04 Markman hearing. The parties will submit this joint statement no later than 2/9/04. Nothing in this Ordershould be construed to otherwise alter the briefing schedule for claim construction.(el,) (Entered: 01/29/2004)
01/28/2004	138	NOTICE OF MOTION AND MOTION to Compel Defendant Genentech Inc.s Responses to First Set of Requests for Production of Documents and First Set of Interrogatories filed by Plaintiff Medimmune Inc. Motion set for hearing on 2/23/2004 at 10:00 AM before Honorable Mariana R. Pfaelzer. (yi,) (Entered: 02/05/2004)
02/02/2004	137	STIPULATION AND ORDER by Judge Mariana R. Pfaelzer : re Page limits for Claim Construction Briefs per Order, 133; that Defendant Genentech, Inc shall file and serve its opening brief concerning claim construction on 12/22/03. Genentechs brief shall not exceed 45 pages; Plaintiff MedImmune Inc shall file and serve its opposition brief on 1/16/04. Medimmunes opposition brief shall not exceed 45 pages: Defendant Genentech Inc shall file and

DATE	NO.	PROCEEDINGS
		serve its reply brief concerning claim construction on 1/27/04.(el,) (Entered: 02/04/2004)
02/06/2004	140	NOTICE OF MOTION AND MOTION for Joinder in [127] MOTION for Entry of Judgment filed by Defendant Genentech Inc. Motion set for hearing on 2/23/2004 at 10:00 AM before Honorable Mariana R. Pfaelzer. (el,) (Entered: 02/11/2004)
02/06/2004	141	STATEMENT filed by Plaintiff Medimmune Inc in response to Defendant Celltech R and D Ltds MOTION for Entry of Final Judgment [127]. (el,) (Entered: 02/11/2004)
02/09/2004	142	SUPPLEMENTAL MEMORANDUM OF LAW in Support of its MOTION to Compel Defendants [138] Genentechs responses to first set of requests for production of documents and interrogatories filed by Plaintiff Medimmune Inc. (el,) (Entered: 02/13/2004)
02/09/2004	143	JOINT STATEMENT responsive to Courts 1/28/04 Order filed by Defendants Celltech R&D Ltd, City of Hope National Medical Center, Genentech Inc, Plaintiff Medimmune Inc re: Order on terms to be construed at Markman Hearing 133. (el,) (Entered: 02/13/2004)
02/09/2004	144	SUPPLEMENTAL MEMORANDUM IN RESPONSE filed by Defendant Genentech Inc to MOTION to Compel[138] (el,) (Entered: 02/13/2004)

DATE	NO.	PROCEEDINGS
02/13/2004	146	REPLY BRIEF FILED by Defendant Genentech Inc regarding Claim Construction Brief [113]. (el,) (Entered: 02/19/2004)
02/13/2004	147	SUPPLEMENTAL DECLARATION of Dean G Dunlavey in support of Defendant Genentech Incs Reply Brief regarding Claim Construction [146] filed by Defendant Genentech Inc. (el,) (Entered: 02/19/2004)
02/13/2004	149	REPLY BRIEF in support of its MOTION for Entry of Final Judgment [127] filed by Defendant Celltech R&D Ltd. (el,) (Entered: 02/20/2004)
02/13/2004	152	JOINDER filed by Defendant City of Hope National Medical Center joining in Brief regarding Claim Construction [146]. (el,) (Entered: 03/03/2004)
02/18/2004	145	MEMORANDUM OF DECISION and ORDER by Judge Mariana R. Pfaelzer : On 1/20/03, Defendant Celltech R&D ("Celltech") filed a Motion for Entry of Final Judgment [127] and [140] Motion for Joinder on said motion. Having determined that oral argument will not assist the Court in considering this motion, this Court hereby vacates the hearing scheduled for 2/23/04, and GRANTS Celltechs motion. This Court enters final judgment on the fifth, sixth, seventh, eighth, ninth and tenth causes of action. Medimmune may pursue the remaining claims, but Celltech will no longer be involved as a party. (el,) (Entered: 02/19/2004)

DATE	NO.	PROCEEDINGS
02/18/2004	148	MEMORANDUM OF DECISION by Judge Mariana R. Pfaelzer regarding Motion to file Second Amended Complaint. That based on this Court's prior summary judgment decision, and in light of the fact that MedImmune's proposed amendments were unduly delayed and would be futile if allowed, MedImmunes [121], Motion for Leave to File Second Amended Complaint is DENIED in its entirety.(el,) (Entered: 02/19/2004)
02/19/2004	150	MINUTES held before Judge Mariana R. Pfaelzer : The Court, on its own Motion, continues Plaintiffs Motion to Compel Genentech responses to 1st set of interrogatories [138], and Markman hearing re: claim construction to 3/15/2004 at 10:00 AM before Honorable Mariana R. Pfaelzer. Court Reporter: Not Present. (el,) (Entered: 02/23/2004)
03/04/2004	158	NOTICE OF APPLICATION to Clerk to Tax Costs on Plaintiff Medimmune Inc filed by Defendant Celltech R&D Ltd. Lodged Bill of Cost. (el,) (Entered: 03/24/2004)
03/08/2004	153	JOINT APPLICATION Requesting a telephonic status conference to discuss subject matter jurisdiction and scheduling in light of the 3/5/04 decision of the Federal Circuit in Gen-Probe Inc v Vysis Inc filed by Defendant Genentech Inc. Lodged proposed order. (el,) (Entered: 03/11/2004)

DATE	NO.	PROCEEDINGS
03/10/2004	154	MINUTES In Chambers Conference held before Judge Mariana R. Pfaelzer : Held Conference call. Parties discuss rulings in Gen-Probe v. Vysis, The Markman hearing will not be held until the motion to dismiss is resolved. The Court stays the action. Case stayed. Counsel will submit a stipulation and proposed order. Court Reporter: Mark Schweitzer. (el,) (Entered: 03/11/2004)
03/11/2004	159	OPPOSITION to Celltech R&D's APPLICATION to Tax Costs [158] filed by Plaintiff Medimmune Inc. (el,) (Entered: 03/24/2004)
03/11/2004	160	OPPOSITION to Celltech R&D's APPLICATION to Tax Costs [158] filed by Plaintiff Medimmune Inc. (el,) (Entered: 03/24/2004)
03/12/2004	155	JUDGMENT by Judge Mariana R. Pfaelzer, This Court enters FINAL JUDGMENT on the fifth, sixth, seventh, eighth, ninth and tenth causes of action. This Order is final judgment for purposes. It shall be entered pursuant to FRCP 58 AND 79(a) and served upon the parties(pj,) (Entered: 03/15/2004)
03/12/2004	156	STIPULATION AND ORDER the hearing on Defendants motion to dismiss remaining causes of action for lack of subject matter jurisdiction will be held on Monday, April 19, 2004 10:00am. Genentech and/or City of Hope will file Opening brief March 22, 2004, Medimmune will file Opposition brief no later than March 29, 2004. Genetech

DATE	NO.	PROCEEDINGS
		and/or City of Hope Reply Briefs April 4, 2004. All other proceedings and discovery in this matter are stayed pending resolution of the motion to dismiss by Judge Mariana R. Pfaelzer :(pj,) (Entered: 03/15/2004)
03/15/2004	161	RESPONSE filed by defendant Celltech to Medimmune Ines Opposition to APPLICATION to Clerk to Tax Costs[158] . (el,) (Entered: 03/24/2004)
03/15/2004	162	DECLARATION of Jason A Crotty regarding Celltechs APPLICATION to Tax Costs [158] filed by Defendant Celltech R&D Ltd. (el,) (Entered: 03/24/2004)
03/17/2004	157	NOTICE OF APPEAL to Federal Circuit Court filed by plaintiff Medimmune Inc. Appeal of Judgment, 155 Filed On: 3/12/04; Entered On: 3/15/04; Filing fee $255, Paid receipt number 13647. cc: Jeffrey R. Witham; Dewey Ballantine; Carella, Byrne, Bain, Gilfillan, Cecchi, Stewart and Olstein; Latham and Watkins, San Francisco; Latham and Watkins, Los Angeles: Latham and Watkins, Costa Mesa; Keker and Van Nest; Ira and Manella: Morrison and Foerster, Los Angeles; Morrison & Foerster, San Francisco. (weap,) (Entered: 03/17/2004)
03/18/2004	163	BILL OF COSTS. Costs Taxed in amount of $ $6,150.45 in favor of Celltech R and D Ltd and against Medimmune Inc. RE: Judgment, 155 (el,) (Entered: 03/24/2004)

DATE	NO.	PROCEEDINGS
03/18/2004		BILL OF COSTS. Costs Taxed in amount of $ $6,150.45 in favor of Celltech and against Medimmune Inc. RE: Judgment, 155 (el,) (Entered: 03/24/2004)
03/22/2004	164	NOTICE OF MOTION AND MOTION to Dismiss for Lack of Jurisdiction filed by Defendant Genentech Inc. Motion set for hearing on 4/19/2004 at 10:00 AM before Honorable Mariana R. Pfaelzer; Memorandum of Points and Authorities in support. (el,) (Entered: 03/26/2004)
03/23/2004	166	NOTICE OF MOTION AND MOTION for Joinder in [164] MOTION to Dismiss for Lack of Jurisdiction filed by Defendant City of Hope National Medical Center. (yl,) (Entered: 04/08/2004)
03/29/2004		Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re: Appeal to Circuit Court [157]. (ghap,) (Entered: 03/29/2004)
03/29/2004	167	PROOF OF SERVICE filed by Plaintiff Medimmune Inc. Plaintiffs Opposition to Genetech Inc's Motion to Dismiss for Lack of Subject Matter Jurisdiction, etc (see document was further details) was served on 3/29/04. (yi,) (Entered: 04/08/2004)
03/29/2004	170	DECLARATION of Tanya Hunter in Support of Plaintiffs Opposition to Motion to Dismiss for Lack of Jurisdiction[164] filed by Plaintiff Medimmune Inc. (yl,) (Entered: 04/08/2004)

DATE	NO.	PROCEEDINGS
03/29/2004	171	OPPOSITION TO GENETECH [*sic*] INC'S MOTION to Dismiss for Lack of Jurisdiction[164] filed by Plaintiff Medimmune Inc. (yl,) (Entered: 04/08/2004)
04/02/2004	165	NOTICE to Prepare Reporter's Transcript filed by plaintiff Medimmune Inc. (wdc,) (Entered: 04/05/2004)
04/05/2004	172	REPLY BRIEF IN SUPPORT Of MOTION to Dismiss for Lack of Jurisdiction[164] filed by Defendant City of Hope National Medical Center. (yl,) (Entered: 04/09/2004)
04/05/2004	174	REPLY BRIEF in support of MOTION to Dismiss for Lack of Jurisdiction [164] filed by Defendant Genentech Inc. (shb,) (Entered: 04/12/2004)
04/05/2004	175	REQUEST FOR JUDICIAL NOTICE in support of MOTION to Dismiss for Lack of Jurisdiction [164] filed by Defendant Genentech Inc. Request set for hearing on 4/19/2004 at 10:00 AM before Honorable Mariana R. Pfaelzer. (shb,) (Entered: 04/12/2004)
		* * * *
04/13/2004	176	NOTIFICATION by Circuit Court of Appellate Docket Number 04-1300, Federal Circuit Court regarding Appeal to Circuit Court, [157] filed by Medimmune Inc. (cbr,) (Entered: 04/15/2004)

DATE	NO.	PROCEEDINGS
04/19/2004	177	PROCEEDINGS: held before Judge Mariana R. Pfaelzer : 1. Genentechs Motion to dismiss for lack of subject matter jurisdiction. 2. Joinder by defendant City of Hope. 3. Request for judicial notice in support of Motion to dismiss. Hears argument. The court takes the matter under submission and will issue the order. Court Reporter: Gail Peoples. (el,) (Entered: 04/20/2004)
		* * * *
04/22/2004	179	MEMORANDUM OF DECISION AND ORDER by Judge Mariana R. Pfaelzer re MOTION to Dismiss for Lack of Jurisdiction[164]. Because the Gen-Probe decision dictates that this Court does not have subject matter jurisdiction over Medimmunes suit for declaratory judgment, Genetechs Motion is GRANTED and the First, Second, Third and Fourth Causes of Actions are dismissed as to both Genetech and City of Hope. (Made JS-6. Case Terminated)(el,) (Entered: 04/23/2004)
04/26/2004	180	AMENDED MEMORANDUM OF DECISION AND ORDER by Judge Mariana R. Pfaelzer re MOTION to Dismiss for Lack of Jurisdiction [164]. Having considered the parties written and oral argument this court GRANTS the Defendants motion. Because the Gen-Probe decision dictates that this Court does not have subject matter jurisdiction over MedImmunes suit for declaratory judgment, Genentechs Motion is GRANTED and the First, Second, Third and

DATE	NO.	PROCEEDINGS
		Fourth Causes of Actions are dismissed as to both Genetech and City of Hope. (see document for specifics)(el,) (Entered: 04/27/2004)
04/28/2004	181	REQUEST for Entry of Judgment filed by Plaintiff Medimmune Inc. Lodged proposed order. (el,) (Entered: 04/30/2004)
04/29/2004	182	STATEMENT OF NO OPPOSITION re Medimmunes REQUEST for Entry of Judgment [181] filed by Defendant Genentech Inc. (el,) (Entered: 04/30/2004)
04/30/2004	183	ENTRY OF JUDGMENT by Judge Mariana R. Pfaelzer: this Court enters final judgment on the first, second, third and fourth causes of action and hereby dismisses those claims as to both Genentech, Inc. and City of Hope. All claims and all defendants are hereby dismissed. This Order is a final judgment for purposes of Fed.R.Civ.P.54(a). It shall be entered pursuant to Fed. R.Civ.P.58 and 79(a), and served upon the parties.(pbap,) Modified on 5/3/2004 (pbap,). (Entered: 05/03/2004)
04/30/2004	185	STATEMENT of NON OPPOSITION to REQUEST for entry of Judgment[181] filed by defendant City of Hope National Medical Center. (lc,) (Entered: 05/07/2004)
04/30/2004	187	NOTICE OF ERRATA filed by Plaintiff Medimmune Inc correcting Response in Opposition to Motion to dismiss for lack of subject matter jurisdiction [171] (el,) (Entered: 05/12/2004)

DATE	NO.	PROCEEDINGS
05/05/2004	184	NOTICE OF APPEAL to Federal Circuit Court filed by plaintiff Medimmune Inc. Appeal of Judgment, 183 Filed On: 4/30/04; Entered On: 5/3/04; Filing fee $255., Paid receipt number 64898. cc: Jeffrey R. Witham; Dewey Ballantine; Elliot M. Olstein; Latham and Watkins, San Francisco; Latham and Watkins, Los Angeles; Latham and Watkins, Costa Mesa; Keker and Van; Irell and Manella; Morrison and Foerster, Los Angeles; Morrison and Foerster, San Francisco. (weap,) (Entered: 05/05/2004)
05/05/2004	189	APPLICATION to Clerk to Tax Costs on Medimmune Inc Re: Amended Memorandum & Opinion 180; Memorandum & Opinion, 179 filed by Defendant City of Hope National Medical Center. (el,) (Entered: 05/28/2004)
		* * * *
05/12/2004		Transmission of Notice of Appeal and Docket Sheet to US Court of Appeals re: Appeal to Circuit Court, [184]. (ghap,) (Entered: 05/12/2004)
05/12/2004	190	STATEMENT of Non-Opposition to Defendants APPLICATION to Tax Costs re Medimmune Inc [189] filed by Plaintiff Medimmune Inc. (el,) (Entered: 05/28/2004)
05/18/2004	195	NOTICE OF APPLICATION TO CLERK TO TAX COSTS filed by Defendant Genentech Inc. (pj,) (Entered: 06/09/2004)

DATE	NO.	PROCEEDINGS
05/20/2004	191	BILL OF COSTS. Costs Taxed in amount of $ $2,209.41 in favor of City of Hope and against MedImmune Inc. RE: Judgment, 183 (el,) (Entered: 05/28/2004)
05/20/2004	192	BILL OF COSTS. Costs Taxed in amount of $ $2,209.41 in favor of City of Hope and against MedImmune Inc. RE: Judgment, 183 (el,) (Entered: 05/28/2004)
05/26/2004	193	NOTIFICATION by Circuit Court of Appellate Docket Number Federal Circuit Cour, 04-1384 regarding, Appeal to Circuit Court, [184] filed by Medimmune (cbr,) (Entered: 05/28/2004)
05/27/2004	196	OPPOSITION to application to clerk to tax costs[195] filed by Plaintiff Medimmune Inc. (pj,) (Entered: 06/09/2004)
05/28/2004	194	NOTICE OF CLERICAL ERROR Re: Costs Taxed[191] should not have a document number since the same document gets a number under the Bill of Costs event, which in this case is #192. (el,) (Entered: 05/28/2004)
05/28/2004	197	RESPONSE filed by Defendant Genentech Inc to opposition [196] (pj,) (Entered: 06/09/2004)
06/03/2004	198	BILL OF COSTS. Costs Taxed in amount of $ 10,322.56 in favor of Genentech Inc and against Medimmune. RE: Judgment, 183. Counsel stipulate to $10,322.56 with teh [*sic*] understanding that neither side to retax (pj,) (Entered: 06/09/2004)

DATE	NO.	PROCEEDINGS
		* * * *
03/02/2005	200	RECORD ON APPEAL sent to Federal Circuit Court re: Appeal number, 04-1300 Record consists of 1 through 10 volumes, 5 transcripts; 5 brown folders # B0058, B0075, B0089, B0114, B0170; 14 sealed documents # 86, 90, 91, 92, 93, 104, 106, 121, 122, 136, 151, 168, 169, 188. (ghap,) Modified on 3/2/2005 (ghap,). Modified on 3/2/2005 (fvap,). (Entered: 03/02/2005)
10/18/2005	201	ORDER from Federal Circuit filed as to Appeal to Circuit Court, [157] filed by Medimmune Inc, Appeal Number Info from USCA (A-8)[176], CCA # 04-1300. Order received in this district on 10/24/05. Notice of entry of judgment accompanied by opinion. (ghap,) Modified on 10/28/2005 (ghap,). (Entered: 10/28/2005)
11/08/2005	202	MANDATE of 9th CCA filed as to Appeal to Circuit Court [157], Appeal Number Info from USCA (A-8)[176], Appeal to Circuit Court [184], Appeal Number Info from USCA (A-8)[193], CCA # 04-1300 and 04-1384. The appeal is AFFIRMED. Mandate received in this district on 11/17/2005. (jp,) (Entered: 11/22/2005)
12/13/2005	203	Appeal Record Returned from 9th CCA RE: RECORD ON APPEAL sent to Federal Circuit Court re: Appeal number, 04-1300 Record consists of 1 through 10 volumes, 5 transcripts; 5 brown folders # B0058, B0075, B0089, B0114, B0170; 14 sealed documents # 86, 90, 91, 92, 93, 104, 106,

DATE	NO.	PROCEEDINGS
		121, 122, 136, 151, 168, 169, 188. (ghap,) Modified on 3/2/2005 (ghap,). Modified on 3/2/2005 (fvap,). Received: Volume(s): 1 through 10; Transcripts(s): 5; brown folders # 58, 75, 89, 114, 170;14 sealed. (ghap,) (Entered: 12/15/2005)

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

No. 04-1300

DOCKET ENTRIES

MEDIMMUNE

v.

GENENTECH

CONSOLIDATED W/APPEAL(S) 04-1384.
CONSOLIDATED APPEAL(S) DOCKETED: 05/20/04

U.S. District Court
Central District of California

Lower Court/Agency #: 03-CV-2567
Notice of Appeal and Certified List Received: 04/06/04
Notice of Appeal Filed: 03/17/04

* * * *

PROCEEDINGS*

1. Certificate of Interest for Defendant Appellee(s), City of Hope, filed (04/20/04) not served. Received: 04/20/04 (EOD 04/27/04) (SKS) 04-1300

2. Certificate of Interest for Appellee(s), Genentech, Inc. Filed (05/03/04) MS 4/30/04. Received: 05/03/04 (EOD 05/05/04) (SKS) 04-1300

3. Certificate of Interest for Appellant(s), Medimmune, Inc. Filed (04/27/04) MS 4/20/04. Received: 04-27-04 (EOD 05/05/04) (SKS) 04-1300

* Capitals in original entries deleted.

PROCEEDINGS

4. Note to File: Lead Appeal 04-1300 is consolidated with appeal 04-1384 (filed by Medimmune on 5/5/04), Docketed 5/20/04. Filed 05/20/04 (EOD 05/20/04 (AMT) 04-1300

5. Official caption revised. (MS-05/20/04) Filed: 05/20/04 (EOD 05/20/04 (AMT) 04-1300

6. Certificate of compliance pursuant to rule 11(d), received from appellant. (MS-05/21/04) Filed: 05/24/04 (EOD 05-25-04) (LP) 04-1300

7. Certificate of compliance pursuant to rule 11(d), received from appellee(s), Filed (05/25/04) (MS-05/24/04) Received: 05-25-04 (EOD 05/27/04) (SKS) 04-1300

8. Recd Appellee Genentech's certificate of compliance with Federal Circuit Rule 11(d). (MS-05/23/04) Received: 05/24/04 (EOD 05/27/04) (KSH) 04-1300

9. Recd Appellee Celltech R&D LTD. certificate of compliance with rule 11(b). (MS-05/24/04) Received: 05/25/04 (EOD 05/27/04) (KSH) 04-1300

10. Appellant - Unopposed motion for extension of time to file appellant's initial brief. (MS-05/27/04) Filed: 05/28/04 On consent. Action on Motion (11): Granted. Brief is due July 7, 2004. By clerk. Filed: 06/02/04. (EOD 06/02/04 by CLT) The brief is due on 07/07/04. 04-1300

12. Appellee's LTR apprising court of an error made in a revised official caption. (Noted and corrected revised official caption was sent to parties). (MS-06/02/04) Received: 05/27/04 (EOD 06/03/04) (LP) 04-1300

Medimmune, Inc. (Appellant) - Brief of plaintiff-appellant Medimmune, Inc. (MS-07/07/04). Filed: 07/07/04 [042555] (EOD 07/09/04 by VW_) 04-1300

PROCEEDINGS

13. Certificate of compliance with Federal Circit Rule 11(d) by the Plaintiff-Appellant, Medimmune, Inc. (MS-07/02/04) Received: 07/02/04 (EOD 07/19/04) (CTD) 04-1300

14. Appellee - Unopposed motion for City of Hope and Genetech, Inc for an extention of time to file the appellee's brief. (MS-07-27-04) Received: 07/27/04. On consent. Action on motion (15): Granted. By clerk. Brief is due September 15, 2004. By clerk. Filed: 07/28/04 (EOD 07/28/04 by CTD) The brief is due on 09/15/04. 04-1300

16. Appellant - Unopposed motion of Medimmune, Inc. for extention of time to file Appellant's Reply Brief. (MS-08/10/04) Filed: 08/11/04 On consent. Action on motion (17): Motion granted. The brief is due on 10/15/04. By clerk. Filed: 08/12/04 (EOD 08/13/04 by JB) 04-1300

City of Hope [appellee] - Brief of Defendant-Appellee City of Hope (MS-09/14/04). Received: 09/15/04. Rejected: 09/20/04. Corrected Brief due: 10/04/04. [042615] (EOD 09/20/04 by LS_) 04-1300

Celltech R&D, LTD. [appellee] - Brief for Defendant-Appellee Celltech R&D LTD. (MS-09/15/04). Received: 03/16/04. Rejected: 09/20/04. Corrected Brief due: 10/04/04. [042615] (EOD 09/20/04 by LS_) 04-1300

Genentech, Inc. [appellee] Brief of Defendant-Appellee Genentech, Inc. (MS-09/15/04). Received: 09/15/04. Rejected: 09/20/04. Corrected Brief due: 10/04/04. [042615] (EOD: 09/20/04 by LS_) 04-1300

18. Amended certificate of interest for the defendant-appellee, City of Hope. (MS-09/15/04) Received: 09/15/04 (EOD 09/21/04) (CTD) 04-1300

Celltech R&D, LTD. [Appellee] - corrected brief for defendant-appellee Celltech R&D LTD. (MS-09/27/04). Corrected brief received: 09/27/04. Filed: 09/15/04 [042615] (EOD 09/29/04 by LS_) 04-1300

Genentech, Inc. [appellee] - corrected brief of Defendant-Appellee Genentech, Inc. (MS-09/24/04). Corrected brief received: 09/24/04. Filed: 09/15/04. [042615] (EOD 09/29/04 by LS_) 04-1300

City of Hope [appellee] - corrected brief of Defendant-Appellee City of Hope (MS-09/24/04). Corrected brief received: 09/27/04. Filed: 09/14/04. [042615] (EOD 09/29/04 by LS_) 04-1300

19. Appellee's LTR confirming telephone call regarding deadline for filing initial brief. (Noted) (MS-09/23/04) Received: 09/28/04) (EOD 09/30/04) (LP) 04-1300

20. Appellant - Motion to request judicial notice of court records. [NPF] (MS-10/15/04). Filed: 10/15/04 Action on motion (23): Motion granted. By motions panel. Judge: Gajarsa. Filed: 11/24/04. (EOD 11/24/04 by ETW) 04-1300

Medimmune, Inc. [appellant] - Reply brief of Plaintiff-Appellant Medimmune, Inc. (MS-10/15/04). Filed: 10/15/04. [052642] (EOD 10/18/04 by VW_) 04-1300

Medimmune, Inc. [appellant] - Joint appendix (Volumes I-III) (MS-10/25/04). Filed: 10/25/04. [confidential & nonconfidential versions] Entry of appearance notice issued. [052653] (EOD 11/01/04 by LS_) 04-1300

21. Joint statement of compliance with rule 33. (MS-10/26/04) Received: 10/26/04 (EOD 11/02/04) (CTD) 04-1300

22. Amended certificate of interest on behalf of Plaintiff-Appellant, Medimmune, Inc. (HS-11/12/04) Received: 11/12/04 (EOD 11/16/04) (SB) 04-1300

    December 22, 2004 Notice of calendaring issued. Panel 0502E on February 10, 2005 04-1300 (KSH)

24. Recd Appellant's citation of supplemental authority. (Sent to Panel) (HS-01/14/05) Received: 01/14/05 (EOD 01/14/05) (KSH) 04-1300

    February 10, 2005 Submitted after Oral Argument by Harvey Kurzwell and D. Wall, C. Barquist. 04-1300 (KSH) (Newman, Mayer and Clevenger)

25. Record requested from DCT-CD/CA on 02/16/05. Due: 03/04/05. [30] Returned: 11/17/05. Rev (11/17/05 by CLT) 2004-1300

26. Affirmed. Precedential opinion by Newman, J. Judgment entered on 10/18/05. Separate opinion dissenting in part by Clevenger, J. Entered by clerk. (MS-10/18/05) Received: 10/18/05 (EOD 10/18/05) (KSH) 04-1300

27. Appellee's (Celltech) stipulated bill of costs against Appellant, Received. (MS-10/31/05) Filed: 11/01/05 30. Allowable costs: $400.00 11/08/05 (EOD 11/08/05) (CLT) 04-1300

28. Appellee's (City of Hope) stipulated bill of costs against Appellant, Received. (MS-11/01/05) Filed: 11/02/05 31. Allowable costs: $200.00 11/08.05 (EOD 11/08/05 (CLT) 04-1300

29. Appellee's (Genentech, Inc.) stipulated Bill of Costs against Appellant, Received. (MS-11/01/05) Filed: 11/01/05 32. Allowable costs: $750.00 11/08/05 (EOD 11/08/05) (CLT) 04-1300

    Mandate issued to the DCT: 11/08/05. (EOD 11/08/05 by CLT) 04-1300

PROCEEDINGS

33. Petition for writ of certiorari filed 10/18/05. Supreme Court #:05-608. (EOD 11/30/05 by AV) 04/1300. (See entry #35)

Docket entries made after this point were made in the new case management system.

35. Petition for Writ of Certiorari filed 10/18/05. Supreme Court #05-608. Cert. Granted on 02/21/06. REV (02/21/06 by AVV) 2004-1300

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Case No. CV 03-2567

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE NATIONAL MEDICAL CENTER, and CELLTECH R&D LTD.

Defendants.

PLAINTIFF MEDIMMUNE, INC.'S COMPLAINT FOR:

1. Declaratory Judgment;
2. Patent Invalidity;
3. Patent Unenforceability;
4. Non-Infringement;
5. Section 1 of the Sherman Act;
6. Section 2 of the Sherman Act;
7. The Cartwright Act;
8. Section 17200 of the Cal. Bus. & Profs. Code; and
9. Unjust Enrichment.

DEMAND FOR JURY TRIAL

JURISDICTION AND VENUE

1. Plaintiff MedImmune, Inc. ("MedImmune") seeks declaratory relief pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337 and 1338(a). This Court has jurisdiction over the state law claims asserted hereunder pursuant to 28 U.S.C. § 1367. This Court has personal jurisdiction over defendant Genentech, Inc. ("Genentech") based

on its principal place of business in California. This Court has personal jurisdiction over defendant City of Hope National Medical Center ("CHNMC") based on its organization under the laws of the state of California and because its principal place of operation is in California. This Court has personal jurisdiction over defendant Celltech R&D Ltd. ("Celltech") based on its activities in this jurisdiction, including, but not limited to, Celltech's filing of a suit against Genentech under 35 U.S.C. § 146 in the Northern District of California captioned *Celltech R&D Ltd. v. Genentech, Inc.*, Civ. Act 01-3560JCS (N.D. Cal. 2001).

2. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), (c), (d), and 15 U.S.C. §§ 15, 22.

THE PARTIES

3. Plaintiff MedImmune, by and through its undersigned attorneys, brings this action under antitrust, patent, and unfair competition laws against defendants Genentech, CHNMC and Celltech (collectively, "Defendants") seeking to challenge an illegal and anticompetitive agreement between Genentech and Celltech to secure the issuance of an invalid and unenforceable patent. MedImmune seeks declaratory relief that the patent is invalid, unenforceable and/or not infringed by MedImmune's Synagis® product and that MedImmune owes no payments under license agreements with Genentech.

4. MedImmune is a Delaware corporation with its principal place of business in Gaithersburg, Maryland. MedImmune uses biotechnology to develop and produce antibody therapies.

5. MedImmune's most successful product, Synagis®, is used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus ("RSV") in pediatric patients at high risk of RSV disease. RSV infection can be fatal in certain high-risk pediatric patients.

6. Defendant Genentech is a Delaware corporation with its principal place of business in South San Francisco, California.

7. Defendant CHNMC is a California non-for-profit organization with its principal place of operation in Duarte, California. CHNMC is an assignee of the patent at issue in this case.

8. Upon information and belief, Celltech is a British company with its principal place of business in Slough, England. Through an intermediary, the Medical Research Counsel, Celltech sub-licensed MedImmune to use the technology patented in U.S. Patent No. 4,816,397 (the "Boss Patent").

SUMMARY OF THIS ACTION

9. MedImmune has filed this action to challenge an illegal and anticompetitive agreement (the "Agreement") between Genentech and Celltech, two large biotechnology companies, which has the effect of creating a 29-year patent monopoly over what Genentech now claims is the "fundamental technology" required for the artificial synthesis of antibody molecules. MedImmune likewise seeks a declaration that the patent improperly created by this Agreement is invalid, unenforceable and/or not infringed by MedImmune's sale of its antibody product, Synagis®, and that MedImmune owes no payments under license agreements with Genentech.

10. Genentech and Celltech have conceded the existence of the Agreement but to date have refused to make it public. Their refusal to disclose the Agreement is purportedly based on confidentiality grounds, notwithstanding the fact that the alleged "invention" at issue is already twenty years old and is described in issued patents. Nonetheless, the parties' own press releases and public filings about the terms of the Agreement have demonstrated its collusive nature and the fact that it benefits only Celltech and Genentech, while harming competition.

11. The Agreement between Celltech and Genentech was reached in the context of a dispute that began in the United States Patent and Trademark Office ("PTO") between Genentech and Celltech regarding priority of invention. Simply put, Genentech asserted that its assignors had invented the same subject matter claimed by the Boss Patent before Celltech's assignors. Thus, Genentech asserted that the Boss Patent held by Celltech (which had been in effect since 1989) should never have issued and that, instead, a new patent should be granted to Genentech covering this same technology. At the time the Agreement was entered into, the PTO had already rejected Genentech's assertion that it, and not Celltech, was entitled to a patent after conducting an administrative proceeding, known as an interference, that lasted seven years. Additionally, a federal court that considered Genentech's appeal had already rejected Genentech's attempts to obtain summary judgment in its favor.

12. Notwithstanding Celltech's legal victories over Genentech in this controversy, some time prior to March 16, 2001 Celltech and Genentech entered into the Agreement, pursuant to which (a) Genentech was declared the winner of the legal dispute between them and awarded priority of invention; (b) the PTO would immediately be asked to revoke Celltech's Boss Patent; and (c) the PTO would be asked to issue simultaneously a new patent to Genentech substantially identical to the Boss Patent (the "New Cabilly Patent"), but with a fresh 17-year life.

13. By entering the Agreement, Celltech obtained more benefits than it ever could have achieved simply by prevailing in the lawsuit with Genentech. Significantly, a Celltech Annual Report revealed that Genentech agreed to provide Celltech with a "preferential" license to the New Cabilly Patent. Moreover, although Celltech agreed to an immediate revocation of its Boss Patent, upon information and belief, it suffered no monetary harm from doing so. According to a

Celltech press release, Genentech agreed to make Celltech whole for any royalties Celltech would have received had its Boss Patent remained in existence until 2006, when it was to expire. Thus, as part of the Agreement, Genentech agreed to pay Celltech, the nominal "loser" in the legal dispute, the royalties that Celltech would have received had Celltech won. Additionally, Celltech benefits to the extent that Genentech uses the New Cabilly Patent to harm competitors of Celltech.

14. The Agreement thus provided Genentech with monopoly power based on a brand new patent with a full 17-year life that would enable Genentech to deny competitors access to what it asserts to be fundamental technology necessary for the production of monoclonal antibodies.

15. The Agreement has profoundly and fundamentally altered the competitive landscape in the biotechnology industry. Before the Agreement, Celltech had granted its competitors broad access to this technology by liberally licensing its Boss Patent. Upon information and belief, in reliance upon the permissive licensing policy of Celltech and the expectation that the patent would expire in 2006, numerous biotechnology companies, including MedImmune, launched research programs to develop monoclonal antibody products that potentially could provide great health benefits to society.

16. Many of these health and life-enhancing products are now in clinical trials to obtain FDA approval and are being prepared for commercialization. Genentech's New Cabilly Patent is an obstacle that can prevent these new antibody products from coming to market.

17. Genentech is thus in a position to demand a much higher royalty for use of this technology until 2018 (when the New Cabilly Patent will expire). Thus, the Agreement allows Genentech to exclude competitors from the market until 2018 or reap monopoly profits from any licenses which it may

choose to grant. Celltech also benefits from this state of affairs because it has "preferential access" to the New Cabilly Patent and to the extent that the New Cabilly Patent may be used to exclude firms that compete with Celltech.

18. With its New Cabilly Patent in hand, Genentech immediately exercised its illegally obtained monopoly by advising MedImmune that the New Cabilly Patent covers MedImmune's Synagis® product. As a consequence of this assertion, MedImmune began to make and continues to make significant payments to Genentech under an agreement entered into by MedImmune and Genentech on or about June 5, 1997 (the "1997 License Agreement"). This 1997 license Agreement provided rights to various intellectual property, including the patent application that later matured into the New Cabilly Patent. After issuance of the New Cabilly Patent, MedImmune was forced to obtain additional license agreements from Genentech on or about February 7, 2003—at substantial cost—to cover seven new products that MedImmune has been developing (the "2003 License Agreements") (collectively the 1997 and 2003 License Agreements are referred to herein as the "License Agreements").

19. MedImmune now seeks relief from Genentech and Celltech for their activities in violation of Sections 1 and 2 of the Sherman Act, Section 16720 of the California Cartwright Act, Section 17200 of the California Business & Professions Code, and under the common law of unjust enrichment in connection with the illegal and anticompetitive Agreement.

20. MedImmune also seeks a declaration that: (a) the New Cabilly Patent (which is co-owned by Genentech and CHNMC) is invalid; (b) the New Cabilly Patent is unenforceable; (c) MedImmune's sales of its Synagis® product do not infringe any valid claim of the New Cabilly Patent and (d) MedImmune owes no payments to Genentech under the License Agreements.

GENENTECH AND CELLTECH REACH THEIR AGREEMENT AND CREATE THE NEW CABILLY PATENT

21. On April 8, 1983, Shmuel Cabilly, Herbert L Heyneker, William E. Holmes, Arthur D. Riggs and Ronald B. Wetzel (collectively, the "Applicants") filed U.S. Patent Application No. 483,457 (the "Old Cabilly Application"). Upon information and belief, Shmuel Cabilly and Arthur D. Riggs were affiliated with CHNMC, while Herbert L Heyneker, William E. Holmes and Ronald B. Wetzel were affiliated with Genentech. Upon information and belief, interests in this application and any subsequently issued patents were assigned to Genentech and CHNMC.

22. Based on the Old Cabilly Application, on March 28, 1989 the PTO issued U.S. Patent No. 4,816,567 (the "Old Cabilly Patent") to the above named Applicants.

23. On June 10, 1988 the Applicants filed U.S. Patent Application No. 205,419 (the "New Cabilly Application") as a continuation to the Old Cabilly Application.

24. On the same day the Old Cabilly Patent was issued, March 28, 1989, Celltech was issued the Boss Patent.

25. After the Boss Patent was issued, Genentech sought to claim the purported invention of the Boss Patent as its own. Genentech therefore amended its New Cabilly Application by including claims copied from the Boss Patent, which caused the PTO Board of Patent Appeals & Interferences (the "PTO Board") to initiate an interference proceeding to determine priority of invention, *i.e.*, who was first purportedly to invent the subject matter claimed by both Celltech and Genentech.

The Seven Year PTO Interference

26. On February 28, 1991 the PTO Board declared a patent interference between Genentech's New Cabilly Application and the Boss Patent on the basis that both claimed the same purported invention.

27. Genentech and Celltech then spent the next seven years in an adversarial interference proceeding before the PTO Board, each arguing that it was the first to make the purported invention at issue.

28. On August 13, 1998 the PTO Board held that Genentech had failed to carry its burden of proving that it was the first to make the purported invention and therefore held that Celltech's Boss Patent was entitled to priority over the New Cabilly Application.

Genentech Appeals and Discovers "New" Evidence

29. Faced with its loss before the PTO Board, on October 9, 1998 Genentech commenced a civil action, *Genentech, Inc. v. Celltech R & D Ltd.*, Case No. C98-3926 MMC ("Civil Action"), in the United States District Court for the Northern District of California under 35 U.S.C. § 146 to appeal the decision of the PTO Board awarding priority of invention to Celltech.

30. The Civil Action lasted for more than two years, and included extensive depositions, document production and expert disclosure.

31. More than nine years into the dispute, sometime in early 2000, Shmuel Cabilly claimed to have found—for the very first time—a draft patent application dated February 25, 1983 (the "Draft Cabilly Application") in his files in Israel that, according to Genentech, established that Cabilly and his colleagues had invented the technology a mere 30 days before the invention date accorded to the Boss Patent based on its United Kingdom Patent application filing date.

32. Based on the late and highly convenient unearthing of this allegedly critical evidence, Genentech moved the District Court for summary judgment that it should be entitled to priority of invention over Celltech. Genentech argued that because the Draft Cabilly Application contained each and

every element of the claimed invention, and was dated earlier than the Boss priority date of March 25, 1983, Genentech should be awarded priority of invention over Boss because Genentech allegedly demonstrated "conception" of the invention by no later than the date of the draft. Further, Genentech argued that it was "reasonably diligent" in preparing and filing the application, which it conceded was a legal prerequisite to being awarded priority. However, Genentech now relied on the alleged diligence of its attorneys in preparing the patent application and "constructive" reduction to practice, which was different from the theory of inventor diligence and actual reduction to practice it had argued before the PTO Board.

Motive to Collude

33. In opposing Genentech's priority argument in the Civil Action based on the Draft Cabilly Application, Celltech asserted that the draft fell short of satisfying the legal requirements for "conception" in that it did not set forth each and every element of the invention. Additionally, Celltech argued that Genentech had changed its basic theory of the case from what it asserted before the PTO Board, a tactic which is not permitted in appeals from PTO interference proceedings.

34. Genentech responded by pointing out that Celltech's March 25, 1983 United Kingdom Boss Patent application suffered from the same deficiencies, which called into question whether Celltech had actually invented the disputed technology. Separately, Genentech also moved for summary judgment that Celltech was not entitled to the March 25, 1983 priority date because of defects in the United Kingdom Boss Patent application.

35. Thus, the dispute over the Draft Cabilly Application caused each party to argue that the other was not in possession of the "invention" at issue in early 1983. This new posture raised the possibility—which MedImmune contends

is the correct outcome—that neither Genentech nor Celltech was entitled to the patent in question. Genentech and Celltech, which had waged this priority dispute for nine years, should have appreciated the possibility that at the end of a protracted legal battle, neither side would end up with a valid patent. This realization provided a strong motive for the Agreement that they entered.

36. The illegal and anticompetitive Agreement was reduced to writing by Genentech and Celltech sometime after July 31, 2000, when the Court denied Genentech's motions for summary judgment. Upon information and belief, Genentech and Celltech entered into the Agreement with a bad faith intent to limit and injure competition as illustrated by the fact that the Agreement called for Celltech to concede defeat to Genentech and sacrifice the Boss Patent. Celltech did so, notwithstanding the facts that it had just defeated Genentech's summary judgment motions based on the "newly discovered" evidence, and that Celltech had established priority in the PTO after a seven-year proceeding.

37. According to publicly available statements, the Agreement required Genentech to make Celltech whole by compensating Celltech for the royalties it would have received under the Boss Patent. Such "reverse payments" (so-called because they were made by Genentech, the nominal winner in the "settlement," to Celltech, the nominal loser) thus provided Celltech all the benefits it would have received had it preserved the victory it had earned at the PTO Board.

38. Indeed, the Agreement put Celltech in a position *better* than any outcome it could have obtained in litigation. Celltech has publicly admitted that Genentech agreed to give Celltech and its products "preferential access" to Genentech's New Cabilly Patent, which could keep competitors at bay, or at a competitive disadvantage, for *twelve years longer* than Celltech's Boss Patent could have done so.

Genentech and Celltech Submit a Deficient Proposed Order to the District Court

39. The parties submitted a proposed order to the District Court in order to implement their Agreement. The proposed order contained a "finding" that Genentech won the priority controversy *as a matter of law* because the Draft Cabilly Application constituted evidence of "conception" prior to the Boss Patent. In fact, as Celltech had argued successfully in opposition to Genentech's summary judgment motion, the Draft Cabilly Application did no such thing in that it was missing certain key elements of the claimed invention. Having first convinced the Court that the Draft Cabilly Application did not prove conception as a matter of law, Celltech reversed course completely and asked the Court to find that it did.

40. Moreover, the findings in the proposed order were insufficient as a matter of law to declare Genentech the prevailing party. In addition to the requirement that Genentech show "conception" before the Boss priority date, it also was necessary as a matter of well established patent law for Genentech to show "reasonable diligence" during the critical period in order to pre-date the Boss Patent. Despite the fact that both Celltech and Genentech recognized and briefed this legal requirement in connection with the summary judgment motions, the proposed order contained no finding with respect to the essential requirement of "reasonable diligence." Moreover, Celltech's concession was flatly inconsistent with Celltech's previous argument that Genentech was precluded from relying on its proffered theory of "attorney diligence," having failed to raise this issue in the PTO interference proceeding.

41. Other than striking the word "proposal" in the title, the District Court on March 16, 2001 signed without change the proposed order that the parties had submitted jointly in

order to implement their illegal and anticompetitive Agreement (the "Order").

42. The March 16, 2001 Order (drafted by Genentech and Celltech) remanded the case back to the PTO Board for further action consistent with the Agreement. Specifically, the Order directed the PTO Board to do three things: (a) "to vacate the PTO's decision in *Cabilly, et al. v. Boss et al.*, Patent Interference No. 102,572"; (b) "to revoke and vacate United States Patent No. 4,816,397, issued March 28, 1989 to Boss, et al."; and (c) "to grant and issue to Genentech's Inventors (with Genentech as the assignee), *with the issue date being the same as the date of revocation of United States Patent No. 4,816,397* [the Boss Patent], a United States patent . . ." (Emphasis added).

PTO Board Expresses Concerns Regarding the Agreement

43. In response to the District Court's Order, the PTO Board revoked the Boss Patent, but refused to issue the New Cabilly Patent, noting that neither the parties nor the District Court had any authority to compel the PTO to issue a patent, particularly when the administrative examination process had not been completed.

44. The fact that the Agreement called for the instantaneous issuance of the New Cabilly Patent, when the parties well knew that the examination process had not been completed, is further evidence of their bad faith and their intent to prevent the PTO from examining the patentability of the alleged invention.

45. The PTO Board expressed concerns about the parties' Agreement. Among other things, the PTO Board noted that the Agreement effectively created a 29-year patent "We will note that if a patent is issued to Cabilly, its term will begin to run now and the public has already been subject to patent rights of Boss since 1989, and that the interference has been pending since 1991."

46. Additionally, the PTO Board expressed concern that Celltech had seemingly abandoned a winning position. In particular, there was no indication that Celltech had raised with the District Court the issue of whether Genentech's "newly discovered" Draft Cabilly Application should have been precluded from evidence because Genentech had not shown that it was diligent in locating this evidence during the more than seven year interference proceeding before the PTO Board.

47. In response to the PTO's refusal to issue the New Cabilly Patent to Genentech at the same time it revoked the Boss Patent, *Celltech* filed a new federal court action in the United States District Court for the Northern District of California seeking an order directing the PTO to issue a patent to *Genentech*. Thus, it appears that Celltech claimed to be aggrieved by the failure of the PTO to issue a patent to Genentech. Because of the Agreement, however, Celltech's concern was understandable: Not only had Genentech agreed to make Celltech whole for any "lost" royalties from the Boss Patent, but Genentech had also agreed to give Celltech "preferential access" to its New Cabilly Patent; thus, it was now in Celltech's interest to have the New Cabilly Patent issue so that it could jointly dominate the market with Genentech.

Examination of the New Cabilly Application

48. Despite its stated reservations, the PTO Board referred the New Cabilly Application to the examiner, given that a major impediment to the issuance of the patent (namely, the Boss Patent) had now been removed by the Court Order (drafted by Genentech and Celltech) resolving the priority issue.

49. During examination of the New Cabilly Application, while under a duty of candor to the PTO, Genentech engaged in improper conduct by deluging the examiner with a stack of

potentially relevant prior art references and other materials, without directing the examiner to those of most direct relevance. This practice had the effect of "burying" the most relevant prior art. Moreover, Genentech either mischaracterized or failed to cite other important prior art.

50. Genentech also should have, but did not, bring to the PTO's attention the fact that Genentech had previously taken a position about one or more prior art references that contradicted the position that Genentech was then taking before the examiner in order to attempt to obtain issuance of the New Cabilly Patent.

51. For example, Genentech had submitted to the European Patent Office ("EPO") a document in a Notice of Opposition proceeding (EP-B-0120694 (84301996.9)) filed on April 19, 1994 wherein Genentech conveyed a position regarding the significance of *Valle at* [*sic*] *al.*, 300 NATURE 71 (1982) that was contradictory to the position Genentech conveyed to the PTO regarding the significance of that same reference.

52. Had Genentech alerted the PTO to the existence of its earlier position before the EPO when it notified the PTO of the existence of the *Valle* reference, the examiner would have determined that the *Valle* prior art reference is a material reference that anticipates or renders obvious the New Cabilly Patent.

53. Moreover, Genentech attempted, by the express terms of the Agreement, to bypass the examination process altogether by requiring immediate issuance of the New Cabilly Patent. When the PTO Board rebuffed this attempt and referred the matter to the examiner, Genentech was under a duty of candor to disclose to the examiner the significant, material issues as to the patentability of the invention which became known to Genentech no later than during the course of the summary judgment briefing in the Civil Action. Not-

withstanding this duty of candor, Genentech never directed the examiner to these significant patentability issues. Properly considered by a reasonable examiner, these flaws in the so-called "invention" would have been material to the consideration of the examiner and would have resulted in a determination that the claims of the New Cabilly Application were unpatentable.

Issuance of the New Cabilly Patent

54. Subsequent to Genentech's misrepresentations and material omissions to the PTO, the New Cabilly Patent, U.S. Patent No. 6,331,415B1, issued on December 18, 2001.

55. The New Cabilly Patent is titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein." It lists as inventors Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs and Ronald B. Wetzel and Genentech as the assignee. A Certificate of Correction issued by the PTO on June 25, 2002 added CHNMC as an additional assignee.

56. The New Cabilly Patent purports to cover "processes for producing an immunoglobulin or an immunologically functional immunoglobulin fragment . . . in a single [host] cell" and, according to Genentech's press release, purportedly relates to the "fundamental methods and compositions used to produce antibodies by recombinant DNA technology." When injected into humans, these antibody molecules (sometimes referred to as "immunoglobulins) can help prevent disease.

57. On the same day the New Cabilly Patent was issued, Celltech issued a press release revealing some of the terms of its illegal and anticompetitive Agreement with Genentech. Celltech admitted that "Celltech will be compensated by Genentech in terms of income from sales of products which would have been covered by the Boss Patent until its normal expiring date in 2006." Thus, notwithstanding the fact that the Boss patent was revoked by the PTO Board in 2000 (pursuant

to the Agreement of the parties), upon information and belief, Celltech effectively continues to receive royalties until 2006. Receipt of royalties after patent expiration constitutes *per se* patent misuse.

58. Moreover, the Celltech press release notes that Celltech is to receive favored treatment under the New Cabilly Patent. The release says that "Celltech also . . . secured preferential access for its development programes to the Cabilly patent, which covers the production of a broad range of antibody or antibody fragment products, for its 17 year life." However, the parties have not disclosed the precise terms of this "preferential access."

Secrecy and Potentially Improper Filing of Agreement with the PTO

59. Pursuant to 35 U.S.C. § 135(c), any agreement to settle a patent interference proceeding must be filed with the PTO. As the Senate Report related to this legislation explains, "[i]nterference proceedings may be terminated in a manner hostile to the public interest by using patent interference settlement agreements as a means of restricting competition. To make such a practice more difficult the bill requires the filing of such agreements in the Patent Office." Defendants have filed the document under seal, preventing MedImmune and the public from determining the exact terms of the Agreement or even if it was filed within the prescribed time limits. A failure to file an agreement terminating an interference within the prescribed limits will result in a finding that the patent is permanently unenforceable.

60. In a letter dated February 13, 2002, MedImmune requested a copy of the Agreement from Genentech.

61. Genentech denied MedImmune's request for a copy of the Agreement in a letter dated March 24, 2002, stating that "the settlement agreement is a confidential document, and we cannot provide it to you."

62. On May 8, 2002, MedImmune petitioned the PTO for access to this Agreement, and on July 22, 2002, continuing in their efforts to conceal the Agreement from public scrutiny, both Celltech and Genentech opposed MedImmune's petition. To the best of MedImmune's knowledge, the PTO has not yet ruled on MedImmune's request as of the date of this Complaint.

GENENTECH REAPS THE BENEFIT OF THE NEW CABILLY PATENT MONOPOLY

63. In public statements Genentech has taken the position that the New Cabilly Patent is extremely broad. For example, Genentech's vice president of intellectual property, Sean Johnston, has stated "we do not believe that the claims are limited by type of antibody (murine, humanized [90% human sequence] or human) or by host cell type" and that "the recently issued patent broadly covers the co-expression of immunoglobulin heavy and light chain genes in a single host cell." In other words, Genentech asserts that the New Cabilly Patent broadly covers the basic method of artificially producing any monoclonal antibody using recombinant DNA technology in any type of host cell.

64. Consistent with this position, in a letter dated January 7, 2002, Genentech advised MedImmune of its "expectation that MedImmune will pay royalties on sales of its Synagis® antibody product pursuant to the license granted by Genentech under the recently issued U.S. Patent No. 6,331,415 [the New Cabilly Patent]."

65. In a letter dated February 13, 2002, MedImmune disputed this demand for royalty payment and requested an explanation of Genentech's "basis for believing that MedImmune's product would infringe any valid claim of the [New Cabilly] Patent such that royalties would be due" and also requested a copy of the Agreement.

66. Receiving no response to its February 13, 2002 letter and fearing the commencement of patent infringement litigation by Genentech before MedImmune could complete its investigation as to the validity and/or enforceability of the New Cabilly Patent, MedImmune made the requested royalty payment, but in a letter dated March 8, 2002 stated that "[s]uch payment, however, was made under protest and with reservation of all of our rights." MedImmune continues to make such royalty payments on a quarterly basis.

INJURY TO MEDIMMUNE AND COMPETITION

67. The Agreement substantially and adversely affects MedImmune in particular and competition in the biotechnology industry in general by limiting access to what Genentech now claims is the core technology for the production of artificially synthesized antibodies.

68. Prior to the Agreement, Celltech controlled this technology through its interest in the Boss Patent, and had authorized the Medical Research Council in London ("MRC") to grant sublicenses to the Boss Patent, which it did liberally and with minimal field of use restrictions.

69. Upon information and belief, MedImmune was one of many biotechnology companies that obtained a sublicense to the Boss Patent at a previously established royalty rate.

70. However, the Agreement effectively nullified the sublicenses freely granted by MRC to technology that would lose patent protection in 2006, and now leaves companies at the mercy of Genentech to acquire new licenses to the New Cabilly Patent, a patent which will not expire until 2018.

71. Genentech is in a position to use the New Cabilly Patent to force biotechnology companies, including MedImmune, to pay substantial royalties to retain access to the same technology that Celltech (through MRC) had once licensed to them, or simply be denied access altogether.

72. The New Cabilly Patent has damaged MedImmune in the form of the payments to Genentech under the 1997 License Agreement based on sales of Synagis®. (In addition to payments to Genentech on account of the New Cabilly Patent, MedImmune continues to pay royalties to MRC despite revocation of the Boss Patent because the Boss Patent license was part of a package with another patent.) Additionally, MedImmune has, as a practical matter, been compelled—at great cost—to enter into the 2003 License Agreements with Genentech to protect its investments in seven critically important products in various stages of preclinical and clinical trials, including the antibodies Vitaxin and Medi-507, and antibodies against each of EphA2, IL-9, PC-Cell-Derived Growth Factor ("PCDGF), Human Aspartyl (Asparaginyl) BetaHydroxylase ("HAAH"), and Human Metapneumovirus ("hMPV"), which target, among other illnesses, cancer, asthma and other respiratory diseases, rheumatoid arthritis and psoriasis. These substantial payment obligations to Genentech under the License Agreements, on account of the New Cabilly Patent, harm MedImmune's ability to compete in its sale of antibody products.

Relevant Market

73. The relevant market is the fundamental recombinant DNA technology for producing antibodies, including the process for producing an immunoglobulin or an immunologically functional immunoglobulin fragment in a single host cell that is purportedly covered by the claims of the New Cabilly Patent.

74. This technology, as interpreted by Genentech, is an essential component to the commercial manufacture of monoclonal antibodies. Upon information and belief, there is no known commercially viable method for recombinantly producing therapeutic antibody molecules without this technology, assuming that the New Cabilly Patent is as broad as Genentech says it is. If so, upon information and belief, no

known proven alternative to this technology exists currently, and the development of any such alternative would require substantial investment of money, resources and time, and cannot reasonably be expected in the foreseeable future.

75. The relevant geographic market is the entire United States.

Market Effects

76. The unlawful conduct of Genentech and Celltech has required MedImmune and, upon information and belief, other users of this technology to obtain new licenses and/or pay additional and substantial royalties under extant licenses for a term beyond that contemplated under existing patent law, or to be excluded from use of this technology.

77. The unlawful conduct of Genentech and Celltech and the resulting issuance of the New Cabilly Patent has diminished the incentive of MedImmune and other users of the technology to invest in products making use of the technology.

FIRST CAUSE OF ACTION:

DECLARATORY JUDGMENT ON CONTRACTUAL RIGHTS AND OBLIGATIONS

(Against Genentech)

78. MedImmune incorporates the allegations of paragraphs 1 through 77 as if fully set forth herein.

79. An actual controversy has arisen and now exists between the parties concerning the rights and obligations of MedImmune under the terms of the License Agreements. Genentech has demanded that MedImmune make payments under the 1997 License Agreement on the basis that Synagis® would infringe a valid claim of the New Cabilly Patent but for the 1997 License Agreement. MedImmune disputes its obligation to make payments under the 1997

License Agreement because MedImmune's sale of its Synagis® product does not infringe any valid claim of the New Cabilly Patent. The basis for invalidity of the New Cabilly Patent arises under the patent laws of the United States, 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or the judicially created doctrine of obviousness type double patenting.

80. MedImmune hereby seeks a declaratory judgment that it owes no payments under the License Agreements.

SECOND CAUSE OF ACTION:

PATENT INVALIDITY

(Against Genentech and CHNMC)

81. Medimmune incorporates the allegations of paragraphs 1 through 80 as if fully set forth herein.

82. An actual controversy has arisen and now exists between the parties concerning the validity of the New Cabilly Patent.

83. The New Cabilly Patent is invalid because it is anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103.

84. The New Cabilly Patent is invalid based on the judicially created doctrine of obviousness type double patenting and/or under 35 U.S.C. §§ 101 and/or 103.

85. The New Cabilly Patent is invalid under 35 U.S.C. § 112.

86. MedImmune hereby seeks a declaratory judgment that the New Cabilly Patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or under the judicially created doctrine of obviousness type double patenting.

THIRD CAUSE OF ACTION:

PATENT UNENFORCEABILITY

(Against Genentech and CHNMC)

87. MedImmune incorporates the allegations of paragraphs 1 through 86 as if fully set forth herein.

88. An actual controversy has arisen and now exists between the parties concerning the enforceability of the New Cabilly Patent.

89. The New Cabilly Patent is unenforceable due to the patent applicants' inequitable conduct before the PTO. Such conduct included the hiding of critical references by "burying" them in the midst of other references of minimal relevance, failing to cite certain prior art at all or to act with candor regarding the significance of certain prior art, and failing to advise the PTO of previous positions that Genentech had taken with respect to certain prior art which are inconsistent with the positions it then took with respect to that same prior art before the examiner of the New Cabilly Patent. In addition, the inequitable conduct also included the failure to direct the PTO to significant flaws in the patentability of the invention which Genentech became aware of no later than during the course of the Civil Action.

90. MedImmune hereby seeks a declaratory judgment that the New Cabilly Patent is unenforceable.

FOURTH CAUSE OF ACTION:

NON-INFRINGEMENT

(Against Genentech and CHNMC)

91. MedImmune incorporates the allegations of paragraphs 1 through 90 as if fully set forth herein.

92. An actual controversy has arisen and now exists between the parties concerning whether MedImmune's

Synagis® product infringes any valid and enforceable claim of the New Cabilly Patent, but for the 1997 License Agreement.

93. MedImmune hereby seeks a declaratory judgment that, but for the 1997 License Agreement, its Synagis® product does not infringe any valid and enforceable claim of the New Cabilly Patent

FIFTH CAUSE OF ACTION:

SECTION 1 OF THE SHERMAN ACT

(Against Genentech and Celltech)

94. MedImmune incorporates the allegations of paragraphs 1 through 93 as if fully set forth herein.

95. Genentech and Celltech conspired and reached the collusive Agreement that ultimately led to the improper issuance of the New Cabilly Patent.

96. Upon information and belief, the Agreement was entered into with the bad faith intent to harm competition.

97. The Agreement has a direct effect upon interstate trade or commerce.

98. Due to Genentech's and Celltech's anticompetitive behavior, MedImmune, among others in the industry, has been harmed by either being blocked from the market altogether or by being required to make exorbitant payments for use of the technology purportedly covered by the claims of the New Cabilly Patent.

99. The unlawful contact, combination, or conspiracy of Genentech and Celltech has no legitimate business objective and is a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. § 1, *et seq.*

100. Upon information and belief, among other things, the Agreement is a market allocation agreement between horizontal competitors that is anticompetitive and illegal *per se* under Section 1 of the Sherman Act, 15 U.S.C. § 1, *et seq.*

101. Alternatively, the unlawful contract, combination, or conspiracy of Genentech and Celltech unreasonably restrains competition in the relevant market and violates Section 1 of the Sherman Act under the Rule of Reason.

102. Genentech and Celltech are liable under Section 1 of the Sherman Act to MedImmune for damages in an amount to be proven at trial, including, without limitation, all payments made by MedImmune to Genentech on account of the New Cabilly Patent; which damages should be trebled under 15 U.S.C. § 15(a), plus interest costs and expenses, including attorney fees.

SIXTH CAUSE OF ACTION:

SECTION 2 OF THE SHERMAN ACT

(CONSPIRACY TO MONOPOLIZE)

(Against Genentech and Celltech)

103. MedImmune incorporates the allegations of paragraphs 1 through 102 as if fully set forth herein.

104. Genentech and Celltech conspired and reached the collusive Agreement that ultimately led to the improper issuance of the New Cabilly Patent

105. Upon information and belief, the Agreement was entered into with the specific intent to grant a monopoly to Genentech that consists of the exclusive rights to what is asserted to be the fundamental technology embodied in the New Cabilly Patent

106. The Agreement has a direct effect upon interstate trade or commerce.

107. Due to Genentech's and Celltech's anticompetitive behavior, MedImmune, among others in the industry, has been harmed by either being blocked from the market altogether or by being required to make exorbitant payments for use of the technology purportedly covered by the claims of the New Cabilly Patent.

108. The unlawful conspiracy of Genentech and Celltech violates Section 2 of the Sherman Act, 15 U.S.C. § 2, *et seq.*

109. Genentech and Celltech are liable under Section 2 of the Sherman Act to MedImmune for damages in an amount to be proven at trial, including, without limitation, all payments made by MedImmune to Genentech on account of the New Cabilly Patent; which damages should be trebled under 15 U.S.C. § 15(a), plus interest, costs and expenses, including attorney fees.

SEVENTH CAUSE OF ACTION:

SECTION 2 OF THE SHERMAN ACT

(MONOPOLIZATION BY GENENTECH)

(Against Genentech)

110. MedImmune incorporates the allegations of paragraphs 1 through 109 as if fully set forth herein.

111. Upon information and belief, Genentech has monopoly power in the relevant market (as defined above).

112. Upon information and belief, Genentech willfully acquired and/or maintained its market dominance in the relevant market by anticompetitive means.

113. Genentech's willful acquisition and/or maintenance of its monopoly power by anticompetitive means has harmed MedImmune, among others in the industry, by either blocking them from the market altogether or requiring them to make exorbitant payments for use of the technology.

114. Genentech is liable under Section 2 of the Sherman Act to MedImmune for damages in an amount to be proven at trial, including, without limitation, all payments made to date by MedImmune to Genentech on account of the New Cabilly Patent; which damages should be trebled under 15 U.S.C. § 15(a), plus interest, costs and expenses, including attorney fees.

EIGHTH CAUSE OF ACTION:

THE CARTWRIGHT ACT

(UNLAWFUL RESTRAINT OF TRADE)

(Against Genentech and Celltech)

115. MedImmune incorporates the allegations of paragraphs 1 through 114 as if fully set forth herein.

116. Genentech and Celltech improperly conspired and reached the collusive Agreement that ultimately led to the improper issuance of the New Cabilly Patent

117. Upon information and belief, the Agreement was entered into with the bad faith intent to harm competition.

118. The Agreement has a direct effect upon trade or commerce in California.

119. The collusive Agreement has no legitimate pro-competitive business objective and unreasonably harms competition.

120. Due to Genentech's and Celltech's anticompetitive behavior in violation of Section 16720 of the California Cartwright Act, MedImmune has been damaged by, for example, being required to make exorbitant payments for use of the New Cabilly Patent technology. Genentech and Celltech are liable to MedImmune for damages in an amount to be proven at trial; trebled under § 16750, plus interest, costs and expenses, including attorney fees.

NINTH CAUSE OF ACTION:

THE CARTWRIGHT ACT

(CONSPIRACY TO MONOPOLIZE)

(Against Genentech and Celltech)

121. MedImmune incorporates the allegations of paragraphs 1 through 120 as if fully set forth herein.

122. Genentech and Celltech conspired and reached the collusive Agreement that ultimately led to the improper issuance of the New Cabilly Patent.

123. Upon information and belief, the Agreement was entered into with the specific intent to grant a monopoly to Genentech that consists of the exclusive rights to what is asserted to be the fundamental technology embodied in the New Cabilly Patent.

124. The Agreement has a direct effect upon trade or commerce in California.

125. Due to Genentech's and Celltech's anticompetitive behavior, MedImmune, among others in the industry, has been harmed by either being blocked from the market altogether or by being required to make exorbitant payments for use of the technology purportedly covered by the claims of the New Cabilly Patent.

126. The unlawful conspiracy of Genentech and Celltech violates Sections 16720 *et seq.* of the California Cartwright Act.

127. Genentech and Celltech are liable under Section 16720 of the Cartwright Act to MedImmune for damages in an amount to be proven at trial, including, without limitation, all payments made to date by MedImmune to Genentech on account of the New Cabilly Patent; which damages should be trebled under § 16720, plus interest, costs and expenses, including attorney fees.

TENTH CAUSE OF ACTION:

SECTION 17200 OF THE CALIFORNIA BUSINESS & PROFESSIONS CODE

(Against Genentech and Celltech)

128. MedImmune incorporates the allegations of paragraphs 1 through 127 as if fully set forth herein.

129. Upon information and belief, Genentech and Celltech have colluded to obtain the issuance of the New Cabilly Patent, and have engaged in unfair, illegal or fraudulent business practices in violation of Section 17200 of the California Business & Professions Code. Due to the Defendants' unfair business practices, MedImmune has been required to make exorbitant payments for use of the New Cabilly Patent's technology.

130. Genentech and Celltech are liable to MedImmune for restitution of payments made to Genentech on account of the New Cabilly Patent, which payments are continuing, and Genentech should be enjoined from attempting to enforce the New Cabilly Patent and any of the terms of the collusive Agreement.

ELEVENTH CAUSE OF ACTION:

UNJUST ENRICHMENT

(Against Genentech)

131. MedImmune incorporates the allegations of paragraphs 1 through 130 as if fully set forth herein.

132. As a result of the Agreement and improper issuance of the New Cabilly Patent, Genentech has been unjustly enriched in an amount to be proven at trial on account of payments made by MedImmune under the New Cabilly Patent, which payments are continuing.

PRAYER FOR RELIEF

WHEREFORE, plaintiff MedImmune requests that judgment be entered in favor of MedImmune and against Defendants:

1. DECLARING that MedImmune has no obligation to pay royalties to Genentech under the License Agreements because the New Cabilly Patent is invalid and/or unenforceable and/or because MedImmune's sale of its Synagis® product does not infringe any valid claim of the New Cabilly Patent;

2. DECLARING that the New Cabilly Patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or the judicially created doctrine of obviousness type double patenting;

3. DECLARING that MedImmune's sale of its Synagis® product does not infringe any valid and enforceable claim of the New Cabilly Patent;

4. DECLARING that the Agreement between Genentech and Celltech violates Section 1 of the Sherman Act;

5. DECLARING that the Agreement between Genentech and Celltech violates Section 2 of the Sherman Act;

6. DECLARING that the Agreement between Genentech and Celltech violates Section 17200 of the California Business & Professions Code;

7. DECLARING that the Agreement between Genentech and Celltech violates Section 16720 of the Cartwright Act;

8. ENJOINING Genentech and/or CHNMC from enforcing the New Cabilly Patent;

9. AWARDING MedImmune damages resulting from Genentech's unjust enrichment;

10. AWARDING MedImmune actual and exemplary damages resulting from Genentech's and Celltech's anti-competitive use of the New Cabilly Patent, including, without limitation, treble damages under 15 U.S.C. § 15(a), Section 16750 of the California Cartwright Act, and such other exemplary damages as are available at law, including those available on account of Genentech's and Celltech's oppression, fraud, or malice; attorney fees; and costs; and

11. PROVIDING MedImmune such other and further relief as the Court may deem just and proper under the circumstances.

Date: April 11, 2003

DEWEY BALLANTINE LLP

By: /s/ Jeffrey R. Witham
JEFFREY R. WITHAM
Attorneys for Plaintiff MEDIMMUNE, INC.

DEMAND FOR JURY TRIAL

Plaintiff Medimmune, Inc. hereby demands a jury trial as provided by Rule 38(a) of the Federal Rules of Civil Procedure.

DEWEY BALLANTINE LLP

By: /s/ Jeffrey R. Witham
JEFFREY R. WITHAM
Attorneys for Plaintiff MEDIMMUNE, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

Case No. CV 03-02567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC, CITY OF HOPE NATIONAL MEDICAL CENTER, AND CELLTECH R&D LTD.,

Defendants.

CELLTECH R&D LTD'S ANSWER

DEMAND FOR JURY TRIAL

Defendant Celltech R&D Ltd. ("Celltech") hereby answers the Complaint of MedImmune, Inc. ("MedImmune") and alleges as follows:

Jurisdiction and Venue

1. Celltech admits that the Complaint purports to state a claim for declaratory relief pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §§ 2201 and 2202. Celltech further admits that it filed a complaint in the United States District Court for the Northern District of California captioned *Celltech R&D Ltd. v. Genentech, Inc.*, Civ. Act. 01-3560 JCS. Celltech admits, on information and belief, that Genentech, Inc. ("Genentech") has its principal place of business in South San Francisco, California. Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments concerning the principal place of business and place of organization of City of Hope National Medical Center ("City of Hope"). Celltech denies all other averments of Paragraph 1, except that inasmuch as the averments of jurisdiction

purport to state legal conclusions, no response thereto is required.

2. Celltech denies the averments of Paragraph 2, except that inasmuch as the averments of venue purport to state legal conclusions, no response thereto is required.

The Parties

3. Celltech admits that the Complaint purports to state claims under the cited legal theories, but denies that Plaintiff is entitled to any relief under those causes of action. Celltech denies all other averments of Paragraph 3, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

4. Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 4, and on that basis denies those averments.

5. Celltech admits that Plaintiff sells a product under the name Synagis. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 5, and on that basis denies those averments.

6. Celltech admits on information and belief that Genentech is a Delaware corporation with its principal place of business in South San Francisco, California.

7. Celltech admits that U.S. Patent No. 6,331,415 B1 states that City of Hope of Duarte, California is an assignee of the patent. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 7, and on that basis denies those averments.

8. Celltech admits that it is a British company with its principal place of business at 208 Bath Road, Slough, Berkshire, SL 1 WE, United Kingdom. Celltech admits that the Medical Research Council sub-licensed to Medimmune

use of the technology patented in U.S. Patent No. 4,816,397 (the "Boss Patent").

9. Celltech admits that the Complaint includes a demand for declaratory relief, but denies that Plaintiff is entitled to any such relief. Celltech denies each and every other averment set forth in Paragraph 9.

10. Celltech admits that it entered into certain agreements with Genentech to settle a patent interference relating to the Boss Patent and U.S. Patent Application No. 205,419 (the "Cabilly Application"), and to secure for Celltech a non-exclusive license to certain rights under U.S. Patent No. 6,331,415 B1 (the "Cabilly Patent"). Celltech further admits that the details of those agreements are confidential and proprietary. Celltech denies each and every other averment set forth in Paragraph 10.

11. Celltech admits that it entered into certain agreements with Genentech to settle a patent interference relating to the Boss Patent and the Cabilly Application, and to secure for Celltech a limited license to certain rights under the Cabilly Patent. Celltech further admits that it prevailed in the patent interference (Interference No. 102,572) before the PTO Board of Patent Interferences and Appeals and that Judge Maxine M. Chesney of the United States District Court for the Northern District of California denied Genentech's motion for summary judgment in the § 146 interference proceeding that was initiated by Genentech. Celltech denies each and every other averment set forth in Paragraph 11.

12. Celltech admits that, prior to March 16, 2001, it entered into certain agreements with Genentech to settle legal proceedings relating to Boss Patent and the Cabilly Application, and to secure for Celltech a limited license to certain rights under the Cabilly Patent. Celltech denies each and every other averment set forth in Paragraph 12.

13. Celltech admits that its 2001 Annual Report states that "Celltech has secured preferential access for its development programmes to the Cabilly patent, which covers the production of a broad range of antibody or antibody fragment products, for its 17 year life." Celltech further admits that a Celltech press release dated December 18, 2001 states: "By this settlement, Celltech will be compensated by Genentech in terms of income from sales of products which would otherwise have been covered by the Boss patent until its normal expiry date in 2006." Celltech denies each and every other averment set forth in Paragraph 13.

14. Inasmuch as the averments of Paragraph 14 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 14, and on that basis denies those averments.

15. Celltech admits that Celltech and the Medical Research Council granted several licenses to the Boss patent. Celltech further admits that the original term of the Boss patent would have expired on March 28, 2006. Celltech denies each and every other averment set forth in Paragraph 15.

16. Inasmuch as the averments of Paragraph 16 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 16, and on that basis denies those averments.

17. Celltech admits that the term of the Cabilly Patent will expire in 2018. Celltech denies each and every other averment set forth in Paragraph 17.

18. Inasmuch as the averments of Paragraph 18 do not relate to Celltech, no response thereto is required. To the

extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 18, and on that basis denies those averments.

19. Celltech admits that the Complaint purports to state claims under the cited statutes and legal theories, but denies that Plaintiff is entitled to any such relief. Celltech denies each and every other averment set forth in Paragraph 19.

20. Celltech admits that the Complaint demands declaratory relief, but denies that Plaintiff is entitled to any such relief. Celltech denies each and every other averment set forth in Paragraph 20.

21. Celltech admits that U.S. Patent No. 4,816,567 states that Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel filed U.S. Patent Application No. 483,457 on April 8, 1983. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 21, and on that basis denies those averments.

22. Celltech admits that U.S. Patent No. 4,816,567 states that it issued on March 28, 1989, based on U.S. Patent Application No. 483,457. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 22, and on that basis denies those averments.

23. Celltech admits that U.S. Patent No. 6,331,415 B1 states that U.S. Patent Application 07/205,419 was filed on June 10, 1988, as a continuation of U.S. Patent Application 06/483,457. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 23, and on that basis denies those averments.

24. Celltech admits that U.S. Patent No. 4,816,567 and U.S. Patent No. 4,816,397 were both issued by the PTO on March 28, 1989.

25. Celltech admits that Genentech amended its Cabilly Application and sought to provoke an interference with the Boss patent. Celltech further admits that Patent Interference No. 102,572 was declared by the PTO on February 28, 1991. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 25, and on that basis denies those averments, except that inasmuch as the averments .purport to state legal conclusions, no response thereto is required.

26. Celltech admits that, on February 28, 1991, the PTO Board of Patent Interferences and Appeals declared Patent Interference No. 102,572 between certain claims of the Cabilly Application and the Boss Patent. Celltech denies each and every other averment set forth in Paragraph 26, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

27. Celltech admits that Patent Interference No. 102,572 was declared on February 28, 1991 and that the final decision of the PTO Board of Patent Appeals and Interferences was issued on August 13, 1998. Celltech admits that both Celltech and Genentech made arguments to the PTO Board of Patent Appeals and Interferences relating to priority of invention. Celltech denies each and every other averment set forth in Paragraph 27.

28. Celltech admits that final decision of the PTO Board of Patent Appeals and Interferences, issued on August 13, 1998, entered judgment in favor of the Celltech inventors, and refers to that decision for its content. Celltech denies each and every other averment set forth in Paragraph 28.

29. Celltech admits that, on October 9, 1998, Genentech initiated a civil action under 35 U.S.C. § 146 entitled

Genentech, Inc. v. Celltech R&D Ltd., Case No. C98-3926 MMC (the "Civil Action"), in the United States District Court for the Northern District of California. Celltech denies each and every other averment set forth in Paragraph 29.

30. Celltech admits that the Civil Action was filed on October 9, 1998 and judgment was entered by the district court on March 16, 2001. Celltech admits that the Civil Action included depositions, document production, and expert disclosures. Celltech denies each and every other averment set forth in Paragraph 30.

31. Celltech admits that, during the course of the Civil Action, Genentech produced a draft patent application. Celltech admits that Genentech made certain contentions regarding the draft patent application, including statements made in Genentech's summary judgment papers filed in the Civil Action, and refers to Genentech's motion papers for their content. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 31, and on that basis denies those averments.

32. Celltech admits that Genentech moved in the Civil Action for summary judgment in its favor, and refers to Genentech's motion papers for their content. Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 32, and on that basis denies those averments, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

33. Celltech admits that it opposed Genentech's motion for summary judgment in the Civil Action, and refers to Genentech's motion papers for their content. Celltech denies each and every other averment set forth in Paragraph 33, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

34. Celltech admits that Genentech filed a reply brief in support of its motion for summary judgment, and refers to Genentech's motion papers for their content. Celltech admits that Genentech filed a motion for summary judgment that Celltech was not entitled to priority to the March 25, 1983 filing date of the United Kingdom Boss patent application, and refers to Genentech's motion papers for their content. Celltech denies each and every other averment set forth in Paragraph 34.

35. Celltech admits that summary judgment motions were filed by Genentech in the Civil Action, and refers to Genentech's motion papers for their content. Celltech denies each and every other averment set forth in Paragraph 35, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

36. Celltech admits that it entered into certain agreements with Genentech to settle a patent interference relating to the Boss Patent and the Cabilly Application, and to secure for Celltech a limited license to certain rights under the Cabilly Patent. Celltech further admits that it prevailed in the patent interference before the PTO Board of Patent Interferences and Appeals and that Judge Maxine M. Chesney of the United States District Court for the Northern District of California denied Genentech's motion for summary judgment in the § 146 interference proceeding that was initiated by Genentech. Celltech denies each and every other averment set forth in Paragraph 36.

37. Celltech denies each and every averment set forth in Paragraph 37, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

38. Celltech denies each and every averment set forth in Paragraph 38, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

39. Celltech admits that in connection with their settlement agreement, Genentech and Celltech submitted a proposed order to the District Court, and that the proposed order contained several proposed findings of fact and conclusions of law, including a proposed finding that "Genentech is entitled as a matter of law to priority over Celltech to invention described by the count." Celltech denies each and every other averment set forth in Paragraph 39, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

40. Celltech denies each and every averment set forth in Paragraph 40, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

41. Celltech admits that the District Court executed the proposed order and entered that Order on March 16, 2001, and refers to the Order for its content. Celltech denies each and every other averment set forth in Paragraph 41.

42. Celltech admits the District Court entered a Judgment in the Civil Action, and refers to the Judgment for its content. Celltech further admits that, among other things, the District Court's Judgment directed the PTO to: "vacate the PTO's decision in *Cabilly et al. v. Boss et al.*, Patent Interference No. 102,572"; "revoke and vacate United States Patent No. 4,816,397, issued March 28, 1989 to Boss *et al.*"; and "grant and issue to Genentech's Inventors (with Genentech as the assignee), with the issue date being the same as the date of revocation of United States Patent No. 4,816,397, a United States patent . . . ." Celltech denies each and every other averment set forth in paragraph 42.

43. Celltech admits that, following entry of the District Court's Judgment, the PTO Board of Patent Interferences and Appeals issued a Final Order After District Court Judgment, and refers to the Final Order for its terms. Celltech denies each and every other averment set forth in Paragraph 43.

44. Celltech denies each and every averment set forth in Paragraph 44.

45. Celltech admits that the PTO Board of Patent Interferences and Appeals' Final Order After District Court Judgment stated, in part, "[w]e will note that if a patent is issued to Cabilly, its term will begin to run now and the public has already been subject to patent rights of Boss since 1989, and that the interference has been pending since 1991." Celltech refers to the Final Order for its terms. Celltech denies each and every other averment set forth in Paragraph 45.

46. Celltech admits that the PTO Board of Patent Interferences and Appeals issued a Final Order After District Court Judgment, and refers to the Final Order for its terms. Celltech denies each and every other averment set forth in Paragraph 46.

47. Celltech admits that it commenced a civil action, *Celltech R&D Ltd. v. Genentech, Inc.*, in the United States District Court for the Northern District of California pursuant to 35 U.S.C. § 146. Celltech denies each and every other averment set forth in Paragraph 47.

48. Celltech admits the PTO Board of Patent Interferences and Appeals referred the Cabilly Application to a patent examiner. Celltech denies each and every other averment set forth in Paragraph 48.

49. Inasmuch as the averments of Paragraph 49 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 49, and on that basis denies those averments.

50. Inasmuch as the averments of Paragraph 50 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is

deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 50, and on that basis denies those averments.

51. Inasmuch as the averments of Paragraph 51 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 51, and on that basis denies those averments.

52. Inasmuch as the averments of Paragraph 52 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 52, and on that basis denies those averments.

53. Inasmuch as the averments of Paragraph 53 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 53, and on that basis denies those averments.

54. Inasmuch as the averments of Paragraph 54 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that U.S. Patent No. 6,331,415 B1, issued on December 18, 2001. Celltech is without knowledge or information sufficient to form a belief as to the truth of every other averment in Paragraph 54, and on that basis denies those averments.

55. Inasmuch as the averments of Paragraph 55 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech

admits that U.S. Patent No. 6,331,415 B1 is titled "Method of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," and lists Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel as inventors. Celltech further admits that the patent lists Genentech as the assignee and that a Certificate of Correction issued by the PTO on June 25, 2002 added City of Hope as an additional assignee. Celltech is without knowledge or information sufficient to form a belief as to the truth of every other averment in Paragraph 55, and on that basis denies those averments.

56. Inasmuch as the averments of Paragraph 56 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that certain antibody molecules can be used to provide beneficial treatment for certain illnesses. Celltech is without knowledge or information sufficient to form a belief as to the truth of every other averment in Paragraph 56, and on that basis denies those averments.

57. Celltech admits that it issued a press release on December 18, 2001, denies that Medimrnune has accurately quoted the press release, and refers to the press release for its terms. Celltech further admits that the press release stated, in part, that "By this settlement, Celltech will be compensated by Genentech in terms of income from sales of products which would otherwise have been covered by the Boss Patent until its normal expiry date in 2006." Celltech denies each and every other averment set forth in Paragraph 57.

58. Celltech admits that it issued a press release on December 18, 2001, denies that Medlmmune has accurately quoted the press release, and refers to the press release for its terms. Celltech further admits that the press release stated, in part, that "Celltech has also secured rights to Genentech's Cabilly patent for its products." Celltech denies each and every other averment set forth in Paragraph 58.

59. Celltech admits the referenced Senate Report contains the quoted language. Celltech further admits that Celltech and Genentech filed their settlement agreement with the PTO under seal pursuant to applicable PTO rules and procedures. Celltech denies each and every other averment of Paragraph 59, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

60. Inasmuch as the averments of Paragraph 60 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 60, and on that basis denies those averments.

61. Inasmuch as the averments of Paragraph 61 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 61, and on that basis denies those averments.

62. Celltech admits that, on May 8, 2002, Plaintiff petitioned the PTO for access to Celltech's and Genentech's settlement agreement, and that Celltech and Genentech opposed that petition. Celltech further states that, on April 4, 2003, the PTO Board of Patent Interferences and Appeals rejected Plaintiff's petition, finding that the petition "appears to constitute a 'fishing expedition' that cannot be granted absent, as respondents have indicated, 'something more' constituting the requisite 'good cause.'" Celltech denies each and every other averment set forth in Paragraph 62.

63. Inasmuch as the averments of Paragraph 63 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 63, and on that basis denies those averments.

64. Inasmuch as the averments of Paragraph 64 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 64, and on that basis denies those averments.

65. Inasmuch as the averments of Paragraph 65 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 65, and on that basis denies those averments.

66. Inasmuch as the averments of Paragraph 66 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 66, and on that basis denies those averments.

67. Celltech denies each and every averment set forth in Paragraph 67.

68. Celltech admits that it owned the Boss patent. Celltech further admits that it granted to the Medical Research Council in London a license to the Boss patent, which license included the right to grant sublicenses, and refers to the sublicenses granted by Medical Research Council for their terms. Celltech denies each and every other averment set forth in Paragraph 68.

69. Celltech admits that Plaintiff, as well as several other individuals and entities, obtained a sublicense to the Boss patent. Celltech denies each and every other averment set forth in Paragraph 69.

70. Celltech denies each and every averment set forth in Paragraph 70.

71. Inasmuch as the averments of Paragraph 71 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 71, and on that basis denies those averments.

72. Inasmuch as the averments of Paragraph 72 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 72, and on that basis denies those averments.

73. Inasmuch as the averments of Paragraph 73 purport to state legal conclusions, no response thereto is required. To the extent a response is required, Celltech denies each and every averment set forth in Paragraph 73.

74. Inasmuch as the averments of Paragraph 74 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 74, and on that basis denies those averments.

75. Inasmuch as the averments of Paragraph 75 purport to state legal conclusions, no response thereto is required. To the extent a response is required, Celltech denies each and every averment set forth in Paragraph 75.

76. Celltech denies that it engaged in unlawful conduct. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 76, and on that basis denies those averments.

77. Celltech denies that it engaged in unlawful conduct. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 77, and on that basis denies those averments.

First Cause of Action
Declaratory Judgment on Contractual Rights and Obligations
(Against Genentech)

78. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 77 of this Answer as if fully set forth herein.

79. Inasmuch as the averments of Paragraph 79 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 79, and on that basis denies those averments.

80. Inasmuch as the averments of Paragraph 80 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Complaint purports to state a claim for declaratory judgment. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 80, and on that basis denies those averments.

Second Cause of Action
Patent Invalidity
(Against Genentech and City of Hope)

81. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 80 of this Answer as if fully set forth herein.

82. Inasmuch as the averments of Paragraph 82 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 82, and on that basis denies those averments.

83. Inasmuch as the averments of Paragraph 83 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 83, and on that basis denies those averments.

84. Inasmuch as the averments of Paragraph 84 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 84, and on that basis denies those averments.

85. Inasmuch as the averments of Paragraph 85 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 85, and on that basis denies those averments.

86. Inasmuch as the averments of Paragraph 86 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Complaint purports to state a claim for declaratory judgment. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 86, and on that basis denies those averments.

Third Cause of Action
Patent Unenforceability
(Against Genentech and City of Hope)

87. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 86 of this Answer as if fully set forth herein.

88. Inasmuch as the averments of Paragraph 88 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 88, and on that basis denies those averments.

89. Inasmuch as the averments of Paragraph 89 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 89, and on that basis denies those averments.

90. Inasmuch as the averments of Paragraph 90 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Complaint purports to state a claim for declaratory judgment. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 90, and on that basis denies those averments.

Fourth Cause of Action
Non-Infringement
(Against Genentech and City of Hope)

91. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 90 of this Answer as if fully set forth herein.

92. Inasmuch as the averments of Paragraph 92 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 92, and on that basis denies those averments.

93. Inasmuch as the averments of Paragraph 93 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Complaint purports to state a claim for declaratory judgment. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 93, and on that basis denies those averments.

Fifth Cause of Action
Section 1 of the Sherman Act
(Against Genentech and Celltech)

94. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 93 of this Answer as if fully set forth herein.

95. Celltech denies each and every averment set forth in Paragraph 95.

96. Celltech denies each and every averment set forth in Paragraph 96.

97. Celltech denies each and every averment set forth in Paragraph 97, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

98. Celltech denies each and every averment set forth in Paragraph 98.

99. Celltech denies each and every averment set forth in Paragraph 99, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

100. Celltech denies each and every averment set forth in Paragraph 100, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

101. Celltech denies each and every averment set forth in Paragraph 101, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

102. Celltech denies that Plaintiff is entitled to any relief under Section 1 of the Sherman Act and denies each and every other averment set forth in Paragraph 101, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Sixth Cause of Action
Section 2 of the Sherman Act (Conspiracy to Monopolize)
(Against Genentech and Celltech)

103. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 102 of this Answer as if fully set forth herein.

104. Celltech denies each and every averment set forth in Paragraph 104.

105. Celltech denies each and every averment set forth in Paragraph 105.

106. Celltech denies each and every averment set forth in Paragraph 106, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

107. Celltech denies each and every averment set forth in Paragraph 107.

108. Celltech denies each and every averment set forth in Paragraph 108, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

109. Celltech denies that Plaintiff is entitled to any relief under Section 2 of the Sherman Act and denies each and every averment set forth in Paragraph 109, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Seventh Cause of Action
Section 2 of the Sherman Act
(Against Genentech)

110. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 109 of this Answer as if fully set forth herein.

111. Inasmuch as the averments of Paragraph 111 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 111, and on that basis denies those averments.

112. Inasmuch as the averments of Paragraph 112 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 112, and on that basis denies those averments.

113. Inasmuch as the averments of Paragraph 113 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 113, and on that basis denies those averments.

114. Inasmuch as the averments of Paragraph 114 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 114, and on that basis denies those averments.

Eighth Cause of Action
The Cartwright Act (Unlawful Restraint of Trade)
(Against Genentech and Celltech)

115. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 114 of this Answer as if fully set forth herein.

116. Celltech denies each and every averment set forth in Paragraph 116.

117. Celltech denies each and every averment set forth in Paragraph 117.

118. Celltech denies each and every averment set forth in Paragraph 118, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

119. Celltech denies each and every averment set forth in Paragraph 119, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

120. Celltech denies that Plaintiff is entitled to any relief under the Cartwright Act and denies each and every other averment set forth in Paragraph 120, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Eighth Cause of Action
The Cartwright Act (Conspiracy to Monopolize)
(Against Genentech and Celltech)

121. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 120 of this Answer as if fully set forth herein.

122. Celltech denies each and every averment set forth in Paragraph 122.

123. Celltech denies each and every averment set forth in Paragraph 123.

124. Celltech denies each and every averment set forth in Paragraph 124, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

125. Celltech denies each and every averment set forth in Paragraph 125.

126. Celltech denies each and every averment set forth in Paragraph 126, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

127. Celltech denies that Plaintiff is entitled to any relief under the Cartwright Act and denies each and every averment set forth in Paragraph 127, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Tenth Cause of Action
Section 17200 of the California Business & Professions Code
(Against Genentech and Celltech)

128. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 127 of this Answer as if fully set forth herein.

129. Celltech denies each and every averment set forth in Paragraph 129, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

130. Celltech denies that Plaintiff is entitled any relief under Section 17200 and denies each and every averment set forth in Paragraph 130, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Eleventh Cause of Action
Unjust Enrichment
(Against Genentech)

131. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 130 of this Answer as if fully set forth herein.

132. Inasmuch as the averments of Paragraph 132 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 132, and on that basis denies those averments.

Affirmative Defenses

As for its further and separate defenses, Celltech states the following affirmative defenses without assuming the burden of proof on such defenses that would otherwise rest on Plaintiff.

First Affirmative Defense

133. The causes of action asserted in the Complaint fail to state a claim upon which relief may be granted.

Second Affirmative Defense

134. Plaintiff has an adequate remedy at law and no basis exists for the grant of equitable relief.

Third Affirmative Defense

135. Plaintiff's causes of action are barred by the Noerr-Pennington doctrine, the First Amendment and/or related doctrines.

Fourth Affirmative Defense

136. Plaintiff's claims are barred for failure to mitigate damages.

Fifth Affirmative Defense

137. Plaintiff's claims are barred to the extent that Plaintiff's purported injuries and damages were not proximately caused by any acts or omissions of Celltech.

Sixth Affirmative Defense

138. The Fifth, Sixth, Seventh and Eighth causes of action should be dismissed because Plaintiff has not suffered, and will not suffer, injury of the type the antitrust laws were designed to prevent.

Seventh Affirmative Defense

139. The equitable doctrine of unclean hands prevents the relief requested by Plaintiff.

Eighth Affirmative Defense

140. Any and all Celltech's conduct challenged by Plaintiff was justified, constituted bona fide business competition, and was carried out in furtherance of Celltech's legitimate business objectives.

Ninth Affirmative Defense

141. The Fifth, Sixth, Seventh and Eighth causes of action are barred by the U.S. patent laws.

Tenth Affirmative Defense

142. Plaintiff's causes of action are barred by the equitable doctrines of waiver, laches, and estoppel.

Eleventh Affirmative Defense

143. Plaintiff lacks standing to the bring [*sic*] causes of action asserted in the Complaint.

Twelfth Affirmative Defense

144. Plaintiff is barred from recovering restitution from Celltech of payments made to Genentech

Prayer for Relief

WHEREFORE, Celltech requests relief as follows:

1. That Plaintiff's claims be dismissed;
2. That Plaintiff take nothing by reason of its Complaint for Damages;
3. That Plaintiff's request for injunctive relief by denied;
4. For the cost of this suit, including reasonable attorneys' fees; and
5. For such other and further relief as the Court may deem proper.

Demand for Jury Trial

Celltech hereby demands a trial by jury for all issues so triable in this action.

Dated: June 4, 2003

LORI A. SCHECHTER
CHARLES S. BARQUIST
JASON A. CROTTY
CHRISTOPHER P. WILLARD
MORRISON & FOERSTER LLP

By: /s/ Charles S. Barquist
CHARLES S. BARQUIST

Attorneys for Defendant
CELLTECH R&D LTD.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Case No. CV03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE NATIONAL MEDICAL CENTER, and CELLTECH R&D LTD.,

Defendants.

GENENTECH, INC.'S NOTICE OF MOTION AND MOTION TO DISMISS THE THIRD AND ELEVENTH CAUSES OF ACTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT

NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE THAT at 10 a.m. on July 21, 2003, or as soon thereafter as the matter can be heard, before the Honorable Mariana R. Pfaelzer, in Courtroom 12 of the United States District Court for the Central District of California, Defendant Genentech, Inc. ("Genentech") will and hereby does move under Federal Rule of Civil Procedure 12(b)(6) for dismissal of plaintiff's Third Cause of Action (Patent Unenforceability) and plaintiff's Eleventh Cause of Action (Unjust Enrichment).

The motion against the Third Cause of Action will be based on the fact that the cause of action fails to state a claim on which relief can be granted because it does not plead inequitable conduct with the particularity required by Federal Rule of Civil Procedure 9(b). In addition, the cause of action

fails to state a claim under Rule 12(b)(6) because it does not allege deceptive intent. The motion against the Eleventh Cause of Action will be based on the fact that the cause of action fails to state a claim on which relief can be granted because it sounds in quasi-contract, and therefore cannot lie because express contracts define the parties' rights on the same subject matter.

This motion is based on this Notice of Motion and Motion, on the Memorandum of Points and Authorities filed concurrently herewith, on the pleadings and papers on file in this action, and on the oral argument at the hearing on the motion.

This motion is made following the conference of counsel pursuant to Local Rule 7-3 which took place on May 28, 2003.

Date: June 4, 2003

Respectfully submitted,

LATHAM & WATKINS LLP
Daniel M. Wall
Mark A. Flagel
James K. Lynch

By /s/ Mark A. Flagel
MARK A. FLAGEL
Attorneys for Defendant
Genentech, Inc.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

Case No. CV-03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH INC., CITY OF HOPE NATIONAL MEDICAL CENTER, and CELLTECH R&D LTD.,

Defendants.

CITY OF HOPE NATIONAL MEDICAL CENTER'S NOTICE OF JOINDER AND JOINDER IN GENENTECH, INC.'S MOTION TO DISMISS THE THIRD CAUSE OF ACTION

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that Defendant City of Hope National Medical Center ("City of Hope") hereby joins in the Motion to Dismiss the Third Cause of Action filed by defendant Genentech, Inc. ("Genentech"). City of Hope is not a defendant on plaintiff Medimmune, Inc.'s, eleventh cause of action, which Genentech also challenges in the motion.

City of Hope respectfully requests the Court to grant the motion to dismiss the third cause of action for the reasons set forth in Genentech's memorandum of points and authorities in support of the motion.

Dated: June 4, 2003 Respectfully submitted,

IRELL & MANELLA LLP
Morgan Chu
David I. Gindler
Joseph M. Lipner

By: /s/ Joseph M. Lipner
JOSEPH M. LIPNER
Attorneys for Defendant
City of Hope National Medical Center

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Aug. 11, 2003]

Case No. CV03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE NATIONAL MEDICAL CENTER, and CELLTECH R&D LTD.,

Defendants.

ORDER GRANTING GENENTECH, INC.'S MOTION TO DISMISS THE THIRD AND ELEVENTH CAUSES OF ACTION

Genentech, Inc.'s motion to dismiss the Third and Eleventh causes of action of MedImmune's Complaint came on for hearing before this Court on August 4, 2003, at 10:00 a.m. in Courtroom 12, Spring Street, with all parties having appeared through counsel.

The Court having reviewed the motion, and after consideration of the opposition and reply papers, arguments of counsel, and all other matters presented to the Court, IT IS HEREBY ORDERED THAT:

The motion is GRANTED as to the Third Cause of Action, and Plaintiff MedImmune has until August 13, 2003 to file and serve a First Amended Complaint The motion is GRANTED as to the Eleventh Cause of Action without leave to amend.

Date: Aug. 11, 2003

/s/ Mariana R. Pfaelzer
HON. MARIANA R. PFAELZER
United States District Judge

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Aug. 13, 2003]

Case No. 03-2567 MRP (CTX)

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.

Defendants.

PLAINTIFF MEDIMMUNE, INC'S FIRST AMENDED COMPLAINT FOR:

1. Declaratory Judgment;
2. Patent Invalidity;
3. Patent Unenforceability;
4. Non-Infringement;
5. Section 1 of the Sherman Act;
6. Section 2 of the Sherman Act;
7. The Cartwright Act;
8. Section 17200 of the Cal. Bus. & Profs. Code.

DEMAND FOR JURY TRIAL

JURISDICTION AND VENUE

1. Plaintiff MedImmune, Inc. ("MedImmune") seeks declaratory relief pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337 and 1338(a). This Court has jurisdiction over the state law claims asserted hereunderpursuant to 28 U.S.C. § 1367. This Court has personal jurisdiction over defendant Genentech, Inc. ("Genentech") based on its principal place of business in California. This

Court has personal jurisdiction over defendant City of Hope ("COH") based on its organization under the laws of the state of California and because its principal place of operation is in California. This Court has personal jurisdiction over defendant Celltech R&D Ltd. ("Celltech") based on its activities in this jurisdiction, including, but not limited to, Celltech's filing of a suit against Genentech under 35 U.S.C. § 146 in the Northern District of California captioned *Celltech R&D Ltd. v. Genentech, Inc.*, Civ. Act 01-3560JCS (N.D. Cal. 2001).

2. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), (c), (d), and 15 U.S.C. §§ 15, 22.

THE PARTIES

3. Plaintiff MedImmune, by and through its undersigned attorneys, brings this action under antitrust, patent, and unfair competition laws against defendants Genentech, COH and Celltech (collectively, "Defendants") seeking to challenge an illegal and anticompetitive agreement between Genentech and Celltech to secure the issuance of an invalid and unenforceable patent. MedImmune seeks declaratory relief that the patent is invalid, unenforceable and/or not infringed by MedImmune's Synagis® product and that MedImmune owes no payments under license agreements with Genentech.

4. MedImmune is a Delaware corporation with its principal place of business in Gaithersburg, Maryland. MedImmune uses biotechnology to develop and produce antibody therapies.

5. MedImmune's most successful product, Synagis®, is used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus ("RSV") in pediatric patients at high risk of RSV disease. RSV infection can be fatal in certain high-risk pediatric patients.

6. Defendant Genentech is a Delaware corporation with its principal place of business in South San Francisco, California.

7. Defendant COH is a California non-for-profit organization with its principal place of operation in Duarte, California. COH is an assignee of the patent at issue in this case.

8. Upon information and belief, Celltech is a British company with its principal place of business in Slough, England. Through an intermediary, the Medical Research Counsel, Celltech sub-licensed MedImmune to use the technology patented in U.S. Patent No. 4,816,397 (the "Boss Patent").

SUMMARY OF THIS ACTION

9. MedImmune has filed this action to challenge an illegal and anticompetitive agreement (the "Agreement") between Genentech and Celltech, two large biotechnology companies, which has the effect of creating a 29-year patent monopoly over what Genentech now claims is the "fundamental technology" required for the artificial synthesis of antibody molecules. MedImmune likewise seeks a declaration that the patent improperly created by this Agreement is invalid, unenforceable and/or not infringed by MedImmune's sale of its antibody product, Synagis®, and that MedImmune owes no payments under license agreements with Genentech.

10. Genentech and Celltech have conceded the existence of the Agreement but to date have refused to make it public. Their refusal to disclose the Agreement is purportedly based on confidentiality grounds, notwithstanding the fact that the alleged "invention" at issue is already twenty years old and is described in issued patents. Nonetheless, the parties' own press releases and public filings about the terms of the Agreement have demonstrated its collusive nature and the fact that it benefits only Celltech and Genentech, while harming competition.

11. The Agreement between-Celltech and Genentech was reached in the context of a dispute that began in the United States Patent and Trademark Office ("PTO" between Genentech and Celltech regarding priority of invention. Simply put, Genentech asserted that its assignors had invented the same subject matter claimed by the Boss Patent before Celltech's assignors. Thus, Genentech asserted that the Boss Patent held by Celltech (which had been in effect since 1989) should never have issued and that, instead, a new patent should be granted to Genentech covering this same technology. At the time the Agreement was entered into, the PTO had already rejected Genentech's assertion that it, and not Celltech, was entitled to a patent after conducting an administrative proceeding, known as an interference, that lasted seven years. Additionally, a federal court that considered Genentech's appeal had already rejected Genentech's attempts to obtain summary judgment in its favor.

12. Notwithstanding Celltech's legal victories over Genentech in this controversy, some time prior to March 16, 2001 Celltech and Genentech entered into the Agreement, pursuant to which (a) Genentech was declared the winner of the legal dispute between them and awarded priority of invention; (b) the PTO would immediately be asked to revoke Celltech's Boss Patent; and (c) the PTO would be asked to issue simultaneously a new patent to Genentech substantially identical to the Boss Patent (the "New Cabilly Patent"), but with a fresh 17-year life.

13. By entering the Agreement, Celltech obtained more benefits than it ever could have achieved simply by prevailing in the lawsuit with Genentech. Significantly, a Celltech Annual Report revealed that Genentech agreed to provide Celltech with a "preferential" license to the New Cabilly Patent. Moreover, although Celltech agreed to an immediate revocation of its Boss Patent, upon information and belief, it suffered no monetary harm from doing so. According to a

Celltech press release, Genentech agreed to make Celltech whole for any royalties Celltech would have received had its Boss Patent remained in existence until 2006, when it was to expire. Thus, as part of the Agreement, Genentech agreed to pay Celltech, the nominal "loser" in the legal dispute, the royalties that Celltech would have received had Celltech won. Additionally, Celltech benefits to the extent that Genentech uses the New Cabilly Patent to harm competitors of Celltech.

14. The Agreement thus provided Genentech with monopoly power based on a brand new patent with a full 17-year life that would enable Genentech to deny competitors access to what it asserts to be fundamental technology necessary for the production of monoclonal antibodies.

15. The Agreement has profoundly and fundamentally altered the competitive landscape in the biotechnology industry. Before the Agreement, Celltech had granted its competitors broad access to this technology by liberally licensing its Boss Patent. Upon information and belief, in reliance upon the permissive licensing policy of Celltech and the expectation that the patent would expire in 2006, numerous biotechnology companies, including MedImmune, launched research programs to develop monoclonal antibody products that potentially could provide great health benefits to society.

16. Many of these health and life-enhancing products are now in clinical trials to obtain FDA approval and are being prepared for commercialization. Genentech's New Cabilly Patent is an obstacle that can prevent these new antibody products from coming to market.

17. Genentech is thus in a position to demand a much higher royalty for use of this technology until 2018 (when the New Cabilly Patent will expire). Thus, the Agreement allows Genentech to exclude competitors from the market until 2018 or reap monopoly profits from any licenses which it may choose to grant. Celltech also benefits from this state of

affairs because it has "preferential access" to the New Cabilly Patent and to the extent that the New Cabilly Patent may be used to exclude firms that compete with Celltech.

18. With its New Cabilly Patent in hand, Genentech immediately exercised its illegally obtained monopoly by advising MedImmune that the New Cabilly Patent covers MedImmune's Synagis® product. As a consequence of this assertion, MedImmune began to make and continues to make significant payments to Genentech under an agreement entered into by MedImmune and Genentech on or about June 5, 1997 (the "1997 License Agreement"). This 1997 License Agreement provided rights to various intellectual property, including the patent application that later matured into the New Cabilly Patent. After issuance of the New Cabilly Patent, MedImmune was forced to obtain additional license agreements from Genentech on or about February 7, 2003—at substantial cost—to cover seven new products that MedImmune has been developing (the "2003 License Agreements") (collectively the 1997 and 2003 License Agreements are referred to herein as the "License Agreements").

19. MedImmune now seeks relief from Genentech and Celltech for their activities in violation of Sections 1 and 2 of the Sherman Act, Section 16720 of the California Cartwright Act and Section 17200 of the California Business & Professions Code in connection with the illegal and anticompetitive Agreement.

20. MedImmune also seeks a declaration that: (a) the New Cabilly Patent (which is co-owned by Genentech and COH) is invalid; (b) the New Cabilly Patent is unenforceable; (c) MedImmune's sales of its Synagis® product do not infringe any valid claim of the New Cabilly Patent; and (d) MedImmune owes no payments to Genentech under the License Agreements.

GENENTECH AND CELLTECH REACH THEIR AGREEMENT AND CREATE THE NEW CABILLY PATENT

21. On April 8, 1983, Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs and Ronald B. Wetzel (collectively, the "Applicants") filed U.S. Patent Application No. 483,457 (the "Old Cabilly Application"). Upon information and belief, Shmuel Cabilly and Arthur D. Riggs were affiliated with COH, while Herbert L. Heyneker, William E. Holmes and Ronald B. Wetzel were affiliated with Genentech. Upon information and belief, interests in this application and any subsequently issued patents were assigned to Genentech and COH.

22. Based on the Old Cabilly Application, on March 28, 1989 the PTO issued U.S. Patent No. 4,816,567 (the "Old Cabilly Patent") to the above named Applicants.

23. On June 10, 1988 the Applicants filed U.S. Patent Application No. 205,419 (the "New Cabilly Application") as a continuation to the Old Cabilly Application.

24. On the same day the Old Cabilly Patent was issued, March 28, 1989. Celltech was issued the Boss Patent.

25. After the Boss Patent was issued, Genentech sought to claim the purported invention of the Boss Patent as its own. Genentech therefore amended its New Cabilly Application by including claims copied from the Boss Patent, which caused the PTO Board of Patent Appeals & Interferences (the "PTO Board") to initiate an interference proceeding to determine priority of invention, *i.e.*, who was first purportedly to invent the subject matter claimed by both Celltech and Genentech.

The Seven Year PTO Interference

26. On February 28, 1991 the PTO Board declared a patent interference between Genentech's New Cabilly Application and the Boss Patent on the basis that both claimed the same purported invention.

27. Genentech and Celltech then spent the next seven years in an adversarial interference proceeding before the PTO Board, each arguing that it was the first to make the purported invention at issue.

28. On August 13, 1998 the PTO Board held that Genentech had failed to carry its burden of proving that it was the first to make the purported invention and therefore held that Celltech's Boss Patent was entitled to priority over the New Cabilly Application.

Genentech Appeals and Discovers "New" Evidence

29. Faced with its loss before the PTO Board, on October 9, 1998 Genentech commenced a civil action, *Genentech, Inc. v. Celltech R & D Ltd.*, Case No. C98-3926 MMC ("Civil Action"), in the United States District Court for the Northern District of California tinder 35 U.S.C. § 146 to appeal the decision of the PTO Board awarding priority of invention to Celltech.

30. The Civil Action lasted for more than two years, and included extensive depositions, document production and expert disclosure.

31. More than nine years into the dispute, sometime in early 2000, Shmuel Cabilly claimed to have found—for the very first time—a draft patent application dated February 25, 1983 (the "Draft Cabilly Application") in his files in Israel that, according to Genentech, established that Cabilly and his colleagues had invented the technology a mere 30 days before the invention date accorded to the Boss Patent based on its March 25, 1983 British Patent Application (the "British Patent Application") filing date.

32. Based on the late and highly convenient unearthing of this allegedly critical evidence, Genentech moved the District Court for summary judgment that it should be entitled to priority of invention over Celltech. Genentech argued that

because the Draft Cabilly Application contained each and every element of the claimed invention, and was dated earlier than the Boss priority date of March 25, 1983, Genentech should be awarded priority of invention over Boss because Genentech allegedly demonstrated "conception" of the invention by no later than the date of the draft. Further, Genentech argued that it was "reasonably diligent" in preparing and filing the application, which it conceded was a legal prerequisite to being awarded priority. However, in the Civil Action, Genentech was relying on the alleged diligence of its attorneys in preparing the patent application and "constructive" reduction to practice, which was different from the theory of inventor diligence and actual reduction to practice it had argued before the PTO Board.

Motive to Collude

33. In opposing Genentech's priority argument in the Civil Action based on the Draft Cabilly Application, Celltech asserted that the draft fell short of satisfying the legal requirements for "conception" in that it did not set forth each and every element of the invention. Additionally, Celltech argued that Genentech had changed its basic theory of the case from what it asserted before the PTO Board, a tactic which is not permitted in appeals from PTO interference proceedings.

34. Genentech responded by pointing out that the Draft Cabilly Application contained at least as much detail as Celltech's March 25, 1983 British Patent Application. Separately, Genentech also moved for summary judgment that Celltech was not entitled to the March 25, 1983 priority date because of defects in the British Patent Application. Genentech's motion thus called into question whether Celltech had actually invented the disputed technology.

35. Thus, the dispute over the Draft Cabilly Application caused each party to argue that the other was not in possession of the "invention" at issue in early 1983. This new

posture meant that Genentech and Celltech each argued that the other was not entitled to the patent in question. Genentech and Celltech, which had waged this priority dispute for nine years, should have appreciated the possibility that at the end of a protracted legal battle, neither side would end up with a valid patent. This realization provided a strong motive for the Agreement that they entered.

36. The illegal and anticompetitive Agreement was reduced to writing by Genentech and Celltech sometime after July 31, 2000, when the Court denied Genentech's motions for summary judgment. Upon information and belief, Genentech and Celltech entered into the Agreement with a bad faith intent to limit and injure competition as illustrated by the fact that the Agreement called for Celltech to concede defeat to Genentech and sacrifice the Boss Patent. Celltech did so, notwithstanding the facts that it had just defeated Genentech's summary judgment motions based on the "newly discovered" evidence, and that Celltech had established priority in the PTO after a seven-year proceeding.

37. According to publicly available statements, the Agreement required Genentech to make Celltech whole by compensating Celltech for the royalties it would have received under the Boss Patent. Such "reverse payments" (so-called because they were made by Genentech, the nominal winner in the "settlement," to Celltech, the nominal loser) thus provided Celltech all the benefits it would have received had it preserved the victory it had earned at the PTO Board.

38. Indeed, the Agreement put Celltech in a position *better* than any outcome it could have obtained in litigation. Celltech has publicly admitted that Genentech agreed to give Celltech and its products "preferential access" to Genentech's New Cabilly Patent, which could keep competitors at bay, or at a competitive disadvantage, for *twelve years longer* than Celltech's Boss Patent could have done so.

Genentech and Celltech Submit a Deficient Proposed Order to the District Court

39. The parties submitted a proposed order to the District Court in order to implement their Agreement. The proposed order contained a "finding" that Genentech won the priority controversy *as a matter of law* because the Draft Cabilly Application constituted evidence of "conception" prior to the Boss Patent. In fact, as Celltech had argued successfully in opposition to Genentech's summary judgment motion, the Draft Cabilly Application did no such thing in that it was missing certain key elements of the claimed invention. Having first convinced the Court that the Draft Cabilly Application did not prove conception as a matter of law, Celltech reversed course completely and asked the Court to find that it did.

40. Moreover, the findings in the proposed order were insufficient as a matter of law to declare Genentech the prevailing party. In addition to the requirement that Genentech show "conception" before the Boss priority date, it also was necessary as a matter of well established patent law for Genentech to show "reasonable diligence" during the critical period in order to pre-date the Boss Patent. Despite the fact that both Celltech and Genentech recognized and briefed this legal requirement in connection with the summary judgment motions, the proposed order contained no finding with respect to the essential requirement of "reasonable diligence." Moreover, Celltech's concession was flatly inconsistent with Celltech's previous argument that Genentech was precluded from relying on its proffered theory of "attorney diligence," having failed to raise this issue in the PTO interference proceeding.

41. Other than striking the word "proposed" in the title, the District Court on March 16, 2001 signed without change the proposed order that the parties had submitted jointly in

order to implement their illegal and anticompetitive Agreement (the "Order").

42. The March 16, 2001 Order (drafted by Genentech and Celltech) remanded the case back to the PTO Board for further action consistent with the Agreement. Specifically, the Order directed the PTO Board to do three things: (a) "to vacate the PTO's decision in *Cabilly, et al. v. Boss et al.*, Patent Interference No. 102,572"; (b) "to revoke and vacate United States Patent No. 4,816,397, issued March 28, 1989 to Boss, et al."; and (c) "to grant and issue to Genentech's Inventors (with Genentech as the assignee), *with the issue date being the same as the date of revocation of United States Patent No. 4,816,397* [the Boss Patent], a United States patent . . ." (Emphasis added).

PTO Board Expresses Concerns Regarding the Agreement

43. In response to the District Court's Order, the PTO Board revoked the Boss Patent, but refused to issue the New Cabilly Patent, noting that neither the parties nor the District Court had any authority to compel the PTO to issue a patent, particularly when the administrative examination process had not been completed.

44. The fact that the Agreement called for the instantaneous issuance of the New Cabilly Patent, when the parties well knew that the examination process had not been completed, is further evidence of their bad faith and their intent to prevent the PTO from examining the patentability of the alleged invention.

45. The PTO Board expressed concerns about the parties' Agreement. Among other things, the PTO Board noted that the Agreement effectively created a 29-year patent: "We will note that if a patent is issued to Cabilly, its term will begin to run now and the public has already been subject to patent rights of Boss since 1989, and that the interference has been pending since 1991."

46. Additionally, the PTO Board expressed concern that Celltech had seemingly abandoned a winning position. In particular, there was no indication that Celltech had raised with the District Court the issue of whether Genentech's "newly discovered" Draft Cabilly Application should have been precluded from evidence because Genentech had not shown that it was diligent in locating this evidence during the more than seven year interference proceeding before the PTO Board.

47. In response to the PTO's refusal to issue the New Cabilly Patent to Genentech at the same time it revoked the Boss Patent, *Celltech* filed a new federal court action in the United States District Court for the Northern District of California seeking an order directing the PTO to issue a patent to Genentech. Thus, it appears that Celltech claimed to be aggrieved by the failure of the PTO to issue a patent to *Genentech*. Because of the Agreement, however, Celltech's concern was understandable: Not only had Genentech agreed to make Celltech whole for any "lost" royalties from the Boss Patent, but Genentech had also agreed to give Celltech "preferential access" to its New Cabilly Patent; thus, it was now in Celltech's interest to have the New Cabilly Patent issue so that it could jointly dominate the market with Genentech.

Examination of the New Cabilly Application:

Inequitable Conduct

48. Despite its stated reservations, the PTO Board referred the New Cabilly Application to a patent examiner to continue prosecution, given that a major impediment to the issuance of the patent (namely, the Boss Patent) had now been removed by the agreement between Genentech and Celltech resolving the priority dispute.

49. Given that the PTO had issued identical claims in 1989 in the form of the Boss Patent, the PTO had no reason to

believe that the claims that Genentech sought in the New Cabilly Application were unpatentable, nor was the PTO given any reason to consider this issue while the interference was still pending. Indeed, the only direction that the PTO Board gave to the PTO examiner was to consider certain references that Genentech had submitted in 1991, *after* the PTO had declared the interference. There is no indication that the PTO examiner handling the matter in 1991 ever considered these references.

50. Thus, after the July 25, 2001 PTO Board decision, prosecution of the New Cabilly Application resumed before a new patent examiner who had no familiarity with the previous prosecution of this application, much less with the interference proceeding in the PTO or the resulting Civil Action.

51. During examination of the New Cabilly Application, while under a duty of candor to the PTO, Genentech and/or COH engaged in inequitable conduct with intent to mislead to PTO in an effort to obtain the New Cabilly Patent.

Patentability Defects

52. Genentech failed to comply with its duty of candor to the PTO because it failed to provide to the PTO examiner meaningful disclosure of the significant, material issues as to the patentability of the claimed invention which became known to Genentech no later than during the course of the summary judgment briefing in the Civil Action.

53. During the course of the Civil Action, Celltech developed and presented expert evidence that cast serious doubt upon whether Genentech's final (or draft) New Cabilly Application enabled the claimed invention, which is a requirement of section 112 of the patent laws. Celltech's expert opined that "Genentech's purported 'conception' lacked a critical component: the Genentech inventors never came up with a workable method for producing 'an Ig [immuno-

globulin] molecule or an immunologically functional Ig fragment' as the [interference] Count requires. Celltech has presented expert testimony . . . showing that Genentech's [final] patent application and laboratory notebooks are completely devoid of a workable conception because of this failing. In particular, Genentech lacked a method for combining ('refolding') the recombinantly expressed heavy and light chain proteins into a functional molecule." Opposition to Genentech's Motion for Summary Adjudication that Genentech Conceived of the Invention Before March 25, 1983 at p. 1. In other words, Celltech offered evidence that Genentech's final New Cabilly Application did not enable the disputed invention as required by 35 U.S.C. § 112.

54. Additionally, Celltech's expert Dr. Jonathan S. Weissman concluded in his expert report (which was quoted in Celltech's Opposition to Genentech's Motion for Summary Adjudication that Genentech Conceived of the Invention Before March 25, 1983) that "Expression of the heavy and light chains from transformed *E. coli* host cells as described in Genentech's patent application does not produce correctly folded Ig molecules or immunogologically functional Ig fragments. . . . [A]s of March 25, 1983, a scientist of ordinary skill in the art would not, without extensive experimentation, have been able to arrive at refolding conditions capable of generating an immunologically functional protein. Indeed, even after extensive experimentation, proper folding conditions may not have been possible to find. Genentech never determined such refolding conditions."

55. *A fortiori*, if Genentech's final New Cabilly Application was insufficient evidence of a complete conception because it lacked a solution to the refolding problem, as Celltech urged, then the Draft Cabilly Application, which was the basis for the settlement, was also insufficient. Indeed, the Draft Cabilly Application had a section heading entitled "Reconstitution [refolding] of Antibody from Recombinant *k*

and Gamma Chains." However, that section of the Draft Cabilly Application was completely blank. Therefore, the Draft Cabilly Application (which formed the basis of Genentech's priority claims in the Civil Action) had absolutely no teaching on a critical part of the purported invention.

56. Thus, no later than the summary judgment briefing, Genentech became aware of evidence raising issues as to the patentability of the New Cabilly Application claims because of a lack of enablement. Such information was material because it would be important for a reasonable PTO examiner to consider any evidence that called into question the patentability of claims sought in prosecution.

57. Genentech responded to Celltech's evidence by asserting that its newly discovered Draft Cabilly Application contained the "same" detail as Celltech's March 25, 1983 British Patent Application, which was the basis for Celltech's claim of priority. Genentech reasoned that if Celltech's 1983 British Patent Application was sufficient to demonstrate enablement of the disputed invention (as Celltech had implicitly argued to the PTO), then the Draft Cabilly Application also must be sufficient because, according to Genentech, it "contains the same information." Genentech's Motion for Summary Adjudication that Genentech Conceived of the Invention Before March 25, 1983.

58. However, at the same time Genentech answered Celltech's attack on the legal sufficiency of the Draft Cabilly Application by *equating* it to Celltech's British Patent Application, Genentech launched its own assault on the legal sufficiency of the very same British Patent Application.

59. Specifically, during Genentech's deposition of Celltech's Expert, Dr. Weissman at pp. 135-36, Genentech asked "[d]o you have any opinion as to whether [Celltech's British Patent Application] would have been sufficient to teach one of ordinary skill how to reassemble the light and heavy chains

as of March 25, 1983," to which Dr. Weissman answered "[i]t's not sufficient."

60. Accordingly, Genentech asserted, "Celltech's British Application was 'not sufficient' to teach one of ordinary skill how to make and use the invention, because . . . the '[f]olding of an immunoglobulin is a difficult problem.' . . As a matter of law, Celltech is not entitled to a priority date based on its [March] 25, 1983 British application." Motion for Summary Adjudication that Celltech is Not Entitled to a Priority Date Based on its British Patent Application.

61. Thus Genentech found itself in the position of arguing (1) that "its February 25, 1983 application contains the *same information* . . as Celltech's British Patent priority document . . . ." Reply Brief Supporting its Motion for Summary Adjudication that Genentech Conceived of the Invention Described by the Court before March 25, 1983, and (2) that Celltech's British Patent Application did not enable the invention in accordance with 35 U.S.C. § 112.

62. The logical conclusion of these two arguments, which *Genentech* made simultaneously, was that Genentech's Draft Cabilly Application was not enabling because it was not sufficient to teach one of ordinary skill how to make and use the invention, specifically with respect to the issue of teaching the "folding" of irnmunoglobulins. .Genentech asserted that Celltech's disclosure was deficient in thus regard, yet in the extensive summary judgment briefing in the Civil Action, Genentech noted that its own disclosure had the "same information" as that of Celltech. Genentech never identified any disclosure relating to refolding in its Draft Cabilly Application (or, indeed in its final application) that provided what Genentech asserted was lacking in Celltech's British Patent Application.

63. Genentech's arguments in the summary judgment briefing (*i.e.* equating the disclosure of its Draft Cabilly Application with that in Celltech's British Patent Application

while simultaneously attacking the sufficiency of that same disclosure) both undercut its position that the Draft Cabilly Application entitled Genentech to priority of invention and demonstrated that Genentech believed that it was essential to have enabling disclosure of refolding in its final New Cabilly Application. Thus, by its own admissions, the issue of refolding was material to the patentability of the claims of the New Cabilly Application.

64. Moreover, the fact that each of Celltech and Genentech was attacking the adequacy of the other application suggested that neither Genentech nor Celltech had properly enabled the invention over which they had fought for nearly ten years. Genentech did not direct the PTO examiner to the fact that Celltech's expert was of the view that neither Genentech nor Celltech had solved the problem of antibody refolding in 1983, the time of the alleged invention.

65. These attacks put the parties on a collision course that could have resulted in neither party emerging from the Civil Action with a valid patent. At the very least, a lengthy public trial developing a detailed factual record concerning these issues would have provided a roadmap for any third party to invalidate whichever patent emerged from the squabble.

66. This collision course gave the parties the motive to enter into a collusive settlement agreement to preserve the patent by agreement. One of the terms of the settlement was that the PTO issue the New Cabilly Patent immediately, and thus without further examination. The PTO Board noted that this was improper. However, the parties' attempt to circumvent the examination process is compelling evidence of the parties' bad faith intent to ensure that there would be no opportunity for the PTO to consider whether the claims were patentable.

67. Once it became aware of the defects in the enablement of the invention, and particularly once patent prosecution resumed before a new examiner after the order of the PTO

Board following the settlement, Genentech had an obligation to reveal the serious questions regarding the patentability of the claimed invention that had come to light during the Civil Action, including a duty to direct the examiner to the expert testimony of Celltech's expert Dr. Jonathan S. Weissman and the admissions that Genentech had itself made (described above) regarding the inadequacy of Genentech's own invention disclosure.

68. Genentech never directed the PTO to these new enablement issues that arose from Celltech's evidence concerning refolding, and from Genentech's own statements, notwithstanding its awareness of the problem and notwithstanding that this would have been material to the examiner in determining whether to issue the patent.

69. This is particularly egregious given that after the New Cabilly Application was sent back for continued examination, as a matter of patent practice and procedure, the new PTO examiner would not *sua sponte* have raised new issues regarding the patentability of the claimed invention under 35 U.S.C. § 112.

70. Therefore, Genentech had a duty to raise the patentability issues to the PTO examiner that had not been previously disclosed to the prior PTO examiner.

71. Indeed, there is no evidence that these issues relating to refolding ever occurred to the new PTO examiner who was charged with assessing the New Cabilly Application in the context of ex parte patent prosecution. Moreover, it was particularly unlikely that the PTO examiner would on his own seek out new issues relating to patentability given the posture of this examination, *i.e.*, the examiner was faced with an order (drafted by Genentech and Celltech) from a United States District Court purporting to direct the PTO to issue a patent to Genentech forthwith and an additional order from the PTO board identifying only the materials submitted in

1991 as a barrier standing in the way of issuance of a patent to Genentech.

72. Under these circumstances, which Genentech orchestrated, Genentech had a duty to advise the examiner of any new issues relating to patentability that had arisen during the decade-long priority dispute.

73. Moreover, because Genentech had equated the disclosure in the Draft Cabilly Application and that in Celltech's British Patent Application, it also should have alerted the PTO examiner to evidence—which Genentech elicited and upon which Genentech relied in the Civil Action—that Celltech's refolding expert believed that Celltech's British Patent Application was deficient. By Genentech's own admission, this was evidence that the Draft Cabilly Application—which Genentech represented contains the *"same information"*—was similarly flawed, thus undercutting the basis for Genentech's priority claim.

74. Having challenged the adequacy of Celltech's disclosure (during the Civil Action) with respect to immunoglobulin refolding, Genentech knew that this refolding issue would have been material to the examiner. Still, Genentech never raised this issue with the examiner.

75. Genentech may claim that it discharged its duty of candor to the PTO by providing the pleadings pertaining to the Civil Action to the PTO and may assert further that the PTO "considered each reference." However, Genentech's dumping of some eleven bankers boxes of pleadings, deposition transcripts, exhibits, affidavits, expert reports and other materials on the PTO *the same day* that the examiner advised Genentech in an interview that he would allow the claims to issue, and just *one day before* the examiner issued the Notice of Allowability of the patent did not satisfy Genentech's duty of candor to the PTO. Genentech never advised the examiner of the significant potential flaws in patentability that had been exposed during the Civil Action.

76. Genentech, well aware of the circumstances of the collusive settlement, attempted to sneak the damaging Civil Action materials into the PTO under circumstances that virtually guaranteed that the examiner would be unable to give them any serious consideration. Genentech made no effort to direct the examiner's attention to any particular materials in the approximately eleven bankers boxes dumped on the PTO at the last minute.

77. Upon information and belief, Genentech submitted the voluminous materials from the Civil Action without saying a word about their contents with intent to deceive and for the express purpose of being able to argue in future patent litigation that the PTO had considered all that occurred in the Civil Action, but nonetheless gave the New Cabilly Patent its approval.

78. Genentech's inequitable conduct, however, did not end with its failure to reveal to the examiner serious non-enablement problems relating to the "refolding" aspect of the claimed invention. Genentech was also responsible for other egregious conduct, including failing to disclose contradictory positions Genentech had taken regarding the significance of material prior art, deluging the examiner with hundreds of prior art references without directing the examiner to those that were most material, and also failing to disclose certain prior art at all, despite having knowledge of such art.

Failure to Disclose Contradictory Positions
On The Vallé Prior Art

79. Genentech failed to disclose to the PTO the fact that it had taken a position about a material prior art reference that contradicted the position that Genentech was taking before the examiner in order to attempt to obtain issuance of the New Cabilly Patent.

80. After declaration of the interference, Genentech submitted a number of references to the PTO examiner in an

Information Disclosure Statement dated September 18, 1991. Genentech cited a number of prior art references disclosing the generation of recombinant immunoglobulin molecules using cells known *as* "oocytes." One of these references was Vallé *et al., Anti-ovalbumin monoclonal antibodies interact with their antigen in internal membranes of Xenopus oocytes,* 300 Nature 71 (1982)("Vallé").

81. In its 1991 filing, Genentech represented that the Vallé article was not invalidating prior art because "[w]ork of this sort is *readily distinguishable* from the instant claims in that the oocytes are not transformed with DNA, but instead are used to transiently express mRNA preparations." (emphasis added).

82. Several years after the submission of Vallé to the PTO, and its representation that Vallé was "readily distinguishable," Genentech made completely inconsistent statements, in another forum, about the significance of this reference. At the same time that Genentech was waging a decade-long priority dispute with Celltech over rights to the invention claimed by the U.S. Boss Patent, Genentech was mounting a separate attack on the validity of the European version of Celltech's Boss Patent (the "European Boss Patent"), which contained the identical specification to Celltech's U.S. Boss Patent and virtually identical claims to the U.S. Boss Patent. Thus, the European Boss Patent claims that Genentech attacked were nearly identical to the claims of the New Cabilly Patent that issued to Genentech in December 2001.

83. In an April 19, 1994 Notice of Opposition proceeding (EP-B-0120694 (84301996.9)) before the European Patent Office ("EPO"), Genentech opposed Celltech's assertion that it was entitled to these patent claims. Genentech submitted a document to the EPO which attacked the validity of these claims based on the same Vallé "oocyte" reference it had distinguished before the U.S. PTO.

84. More particularly, Genentech asserted in Europe that Vallé was material prior art. In the process, Genentech trivialized the distinction between mRNA (messenger RNA), which was used in the Vallé article, and DNA, which was claimed in the European Boss Patent application: "[i]n view of the broad implications evidenced by the Abstract, the fact that the actual experiment was performed with microinjected mRNAs is not relevant. In any event, because the messenger RNA carries the information from DNA to the ribosomal site of protein synthesis, it is *functionally equivalent* to DNA." (emphasis added).

85. This representation was diametrically opposed to Genentech's statements to the PTO. When comparing the same prior art reference against the same claimed subject matter, what was "readily distinguishable" before the PTO became "functionally equivalent" before the EPO.

86. As of April, 1994, while the New Cabilly Application was still pending, (on or in any event no later than July 25, 2001, when the PTO Board directed the PTO to examine the New Cabilly Patent Application), Genentech had a duty to advise the PTO examiner that it had arrived at the conclusion that the use of messenger RNA in Vallé was "functionally equivalent to DNA." Not only would this insight have been material to a reasonable examiner in its own right, but its materiality was enhanced by the fact that Genentech's new position contradicted its representation to the PTO in September 1991 that the Vallé work was "readily distinguishable" because it involved messenger RNA rather than DNA.

87. In its July 25, 2001 order, the PTO Board singled out the 1991 Information Disclosure Statement, which contained Genentech's now contradicted statements about the Vallé reference, for consideration by the examiner when prosecution resumed. Thus, Genentech's 1991 statements were being presented in 2001 to a new examiner responsible for considering the New Cabilly Application. These developments

only heightened Genentech's existing obligation to provide complete disclosure with respect to the material Vallé reference, including disclosure of its 1994 conclusions about this reference and its inconsistent statements about the same reference while opposing Celltech's efforts to obtain nearly identical claims in Europe.

88. Despite its obligation to do so, Genentech never advised the PTO examiner of its 1994 conclusions with respect to the Vallé reference, its EPO statements in that regard, and the fact that its EPO statements directly contradicted what it had told the PTO years earlier. When the PTO Board directed the examiner to consider, in 2001, the Information Disclosure Statement Genentech filed in 1991, Genentech was effectively reaffirming its 1991 representation to the PTO, which it had plainly abandoned no later than 1994.

89. It would have been important for a reasonable examiner to know all these facts about the Vallé reference, which disclosed a recombinant antibody. Genentech itself plainly believed the reference was material to the claimed invention, as demonstrated by Genentech's reliance upon the Vallé reference as the centerpiece of its attack upon the validity of the European Boss claims, which were virtually identical to the claims Genentech was seeking.

90. Because Genentech made affirmative statements to the PTO about this reference in 1991, it was materially misleading for Genentech to fail to tell the PTO about its 1994 positions and its contradictory statements to another patent office about these same references.

91. Based on the protracted high profile legal battle between Genentech and Celltech both in the U.S. and Europe, Genentech's treatment of the Vallé reference in the U.S. (making special efforts to distinguish it) and Europe (basing an invalidity case upon it), Genentech's high level of sophistication, and the extraordinary measures that Genentech

took over many years to secure allowance of the New Cabilly Patent, it is evident that Genentech withheld its contradictory statements about the Vallé reference with an intent to deceive the PTO.

Burying Prior Art

92. Genentech also committed inequitable conduct by deluging the examiner with more than *350* prior art references, in addition to the eleven banker boxes containing the documents related to the Civil Action. Strikingly, in the Information Disclosure Statement dated September 13, 2001 alone, Genentech dumped more than *275* references on the examiner.

93. To put this conduct into perspective, in the thirteen years that passed between Genentech's filing of the New Cabilly Application in 1988 through September 12, 2001, Genentech advised the PTO of approximately 75 prior art references. Then in the last few weeks of prosecution, Genentech submitted more than *275* additional references.

94. Since Genentech submitted such a large number of references, under its duty of candor generally and under the principles summarized in section 2400(13) of the Manual of Patent Examining Procedure, it should have "highlight[ed] those documents which have been specifically brought to the applicants attention and/or are known to be of most significance." Genentech never did this.

95. Moreover, if Genentech had any genuine interest in providing meaningful disclosure to the PTO, it could have begun the disclosure process long before it did so. Genentech understood that the pendency of the interference was no bar to the submission of prior art references, as demonstrated by Genentech's submission of the Vallé reference and other articles concerning oocytes after declaration of the interference. Genentech also could have submitted these references once it got the District Court to sign the jointly

proposed March 16, 2001 order directing the PTO to issue the New Cabilly Patent. The reason Genentech waited until the last minute to disclose these prior art references was, as demonstrated by the March 16, 2001 order drafted by it and Celltech, that Genetech intended to orchestrate the settlement so as to avoid any further examination of the New Cabilly Patent.

96. The dumping of these voluminous and dense prior art references in a single Information Disclosure Statement—just a few weeks before the notice of allowability of the patent was issued on October 5, 2001—and without directing the examiner to those of the greatest significance had the effect of "burying" a material piece of prior art: Stanford University's European Patent Application, EPO No. 0,044,722 (the "Stanford Application").

97. The Stanford Application is a material reference because it teaches the production of recombinant antibodies in bacterial host cells by use of *DNA* encoding the heavy and light chains of an antibody. The Stanford Application teaches a procedure essentially identical to the procedure disclosed in the New Cabilly Application and which formed the basis for the claims in the New Cabilly Patent.

98. It would have been important to a reasonable examiner for Genentech to highlight the significance of the Stanford Application, particularly given Genentech's position before the PTO that Vallé was "readily distinguishable" because it used mRNA instead of DNA. In contrast, the Stanford Application teaches use of DNA, as is claimed in the New Cabilly Patent. Instead, Genentech made no effort to highlight this reference in any way as compared to the approximately 275 other references submitted on the same day.

99. Based on the surrounding circumstances, including the materiality of the Stanford Application, the volume of the references submitted, the timing of such submissions and

Genentech's attempts to avoid any examination of the New Cabilly Application, Genentech buried the Stanford Application with an intent to deceive the PTO.

Failure to Disclose Material Prior Art

100. Genentech also committed inequitable conduct by failing to disclose anywhere among the more than *350* total references critical prior art references that fully anticipate or, in combination with other references, render obvious the claims of the New Cabilly Patent: U.S. Patent No. 4,399,216 (the "'216 Patent"), U.S. Patent No. 4,634,665 (the "'665 Patent") and U.S. Patent No. 5,179,017 (the "'017 Patent") (collectively the "Axel Patents").

101. The Axel Patents are material references because they all disclose a process for inserting DNA into cells to produce proteinaceous materials, and at least the first such patent (the '216 Patent) expressly claimed generation of a recombinant antibody molecule through the transformation of a cell with *DNA*. Thus, Genentech would not have been able to distinguish this reference on the grounds used to distinguish the Vallé reference.

102. Genentech knew of the existence and significance of the '216 Patent and '665 Patent during the prosecution of the New Cabilly Patent because, *inter alia*, it has alleged that it paid some seventy million dollars in royalties on account of those patents (presumably for its recombinant antibody products) for the years 1987 through 2000, according to a complaint that Genentech filed against Columbia University. *See Genentech, Inc. v. The Trustees of Columbia University of the City of New York*, Civ. No. 03-1603 (N.D. Cal. 2003).

103. Upon information and belief, Genentech also knew of the existence of the '017 Patent during prosecution of the New Cabilly Application based on the significant royalties it was paying on its predecessor patents (the '216 Patent and the '665 Patent), and because Genentech alleges that it had a

license with Columbia for "certain" other "patent applications" involving the Axel disclosure.

104. Despite its knowledge of the Axel Patents during the prosecution of the New Cabilly Patent, Genentech never brought the Axel Patents to the examiner's attention.

105. Disclosure of the Axel Patents would have been important to a reasonable examiner in considering the patentability of the New Cabilly Patent claims, given that they all disclose a process for inserting DNA into cells to produce proteinaceous materials, and that the '216 Patent specifically claimed recombinant production of an antibody by use of DNA, the same subject matter claimed in the New Cabilly Patent.

106. Upon information and belief, based on the circumstances surrounding Genentech's omission of the Axel Patents as references, including their materiality for the reasons stated above, Genentech's awareness of these patents and their significance in the recombinant antibody field based on Genentech's large royalty payments to Columbia University, and based on the lengths to which Genentech was willing to go to obtain issuance of the New Cabilly Patent, including entering a collusive settlement agreement that went so far as to command the PTO to issue the New Cabilly Patent without further examination, Genentech omitted the Axel Patents as a prior art references with the intent to deceive the PTO in order to obtain issuance of the New Cabilly Patent.

Issuance of the New Cabilly Patent

107. Subsequent to Genentech's misrepresentations and material omissions to the PTO, the New Cabilly Patent, U.S. Patent No. 6,331,415B1, issued on December 18, 2001.

108. The New Cabilly Patent is titled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein." It lists as inventors Shmuel Cabilly,

Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs and Ronald B. Wetzel and Genentech as the assignee. A Certificate of Correction issued by the PTO on June 25, 2002 added COH as an additional assignee.

109. The New Cabilly Patent purports to cover "processes for producing an immunoglobulin or an immunologically functional immunoglobulin fragment . . . in a single [host] cell" and, according to Genentech's press release, purportedly relates to the "fundamental methods and compositions used to produce antibodies by recombinant DNA technology." When injected into humans, these antibody molecules (sometimes referred to as "immunoglobulins") can help prevent disease.

110. On the same day the New Cabilly Patent was issued, Celltech issued a press release revealing some of the terms of its illegal and anticompetitive Agreement with Genentech. Celltech admitted that "Celltech will be compensated by Genentech in terms of income from sales of products which would have been covered by the Boss Patent until its normal expiring date in 2006." Thus, notwithstanding the fact that the Boss patent was revoked by the PTO Board in 2000 (pursuant to the Agreement of the parties), upon information and belief, Celltech effectively continues to receive royalties until 2006. Receipt of royalties after patent expiration constitutes *per se* patent misuse.

111. Moreover, the Celltech press release notes that Celltech is to receive favored treatment under the New Cabilly Patent. The release says that "Celltech also . . . secured preferential access for its development programes to the Cabilly patent, which covers the production of a broad range of antibody or antibody fragment products, for its 17 year life." However, the parties have not disclosed the precise terms of this "preferential access."

Secrecy and Potentially Improper Filing of Agreement with the PTO

112. Pursuant to 35 U.S.C. § 135(c), any agreement to settle a patent interference proceeding must be filed with the PTO. As the Senate Report related to this legislation explains, "[i]nterference proceedings may be terminated in a manner hostile to the public interest by using patent interference settlement agreements as a means of restricting competition. To make such a practice more difficult the bill requires the filing of such agreements in the Patent Office." Defendants have filed the document under seal, preventing MedImmune and the public from determining the exact terms of the Agreement or even if it was filed within the prescribed time limits. A failure to file an agreement terminating an interference within the prescribed limits will result in a finding that the patent is permanently unenforceable.

113. In a letter dated February 13, 2002, MedImmune requested a copy of the Agreement from Genentech.

114. Genentech denied MedImmune's request for a copy of the Agreement in a letter dated March 24, 2002, stating that "the settlement agreement is a confidential document, and we cannot provide it to you."

115. On May 8, 2002, MedImmune petitioned the PTO for access to this Agreement, and on July 22, 2002, continuing in their efforts to conceal the Agreement from public scrutiny, both Celltech and Genentech opposed MedImmune's petition. The PTO denied MedImmune's request for access to the Agreement.

GENENTECH REAPS THE BENEFIT OF THE NEW CABILLY PATENT MONOPOLY

116. In public statements Genentech has taken the position that the New Cabilly Patent is extremely broad. For example, Genentech's vice president of intellectual property, Sean

Johnston, has stated "we do not believe that the claims are limited by type of antibody (murine, humanized [90% human sequence] or human) or by host cell type" and that "the recently issued patent broadly covers the co-expression of immunoglobulin heavy and light chain genes in a single host cell." In other words, Genentech asserts that the New Cabilly Patent broadly covers the basic method of artificially producing any monoclonal antibody using recombinant DNA technology in any type of host cell.

117. Consistent with this position, in a letter dated January 7, 2002, Genentech advised MedImmune of its "expectation that MedImmune will pay royalties on sales of its Synagis® antibody product pursuant to the license granted by Genentech under the recently issued U.S. Patent No. 6,331,415 [the New Cabilly Patent]."

118. In a letter dated February 13, 2002, MedImmune disputed this demand for royalty payment and requested an explanation of Genentech's "basis for believing that MedImmune's product would infringe any valid claim of the [New Cabilly] Patent such that royalties would be due" and also requested a copy of the Agreement.

119. Receiving no response to its February 13, 2002 letter and fearing the commencement of patent infringement litigation by Genentech before MedImmune could complete its investigation as to the validity and/or enforceability of the New Cabilly Patent, MedImmune made the requested royalty payment, but in a letter dated March 8, 2002 stated that "[s]uch payment, however, was made under protest and with reservation of all of our rights." MedImmune continues to make such royalty payments on a quarterly basis.

INJURY TO MEDIMMUNE AND COMPETITION

120. The Agreement substantially and adversely affects MedImmune in particular and competition in the biotechnology industry in general by limiting access to what Genen-

tech now claims is the core technology for the production of artificially synthesized antibodies.

121. Prior to the Agreement, Celltech controlled this technology through its interest in the Boss Patent, and had authorized the Medical Research Council in London ("MRC") to grant sublicenses to the Boss Patent, which it did liberally and with minimal field of use restrictions.

122. Upon information and belief, MedImmune was one of many biotechnology companies that obtained a sublicense to the Boss Patent at a previously established royalty rate.

123. However, the Agreement effectively nullified the sublicenses freely granted by MRC to technology that would lose patent protection in 2006, and now leaves companies at the mercy of Genentech to acquire new licenses to the New Cabilly Patent, a patent which will not expire until 2018.

124. Genentech is in a position to use the New Cabilly Patent to force biotechnology companies, including MedImmune, to pay substantial royalties to retain access to the same technology that Celltech (through MRC) had once licensed to them, or simply be denied access altogether.

125. The New Cabilly Patent has damaged MedImmune in the form of the payments to Genentech under the 1997 License Agreement based on sales of Synagis®. (In addition to payments to Genentech on account of the New Cabilly Patent, MedImmune continues to pay royalties to MRC despite revocation of the Boss Patent because the Boss Patent license was part of a package with another patent.) Additionally, MedImmune has, as a practical matter, been compelled—at great cost—to enter into the 2003 License Agreements with Genentech to protect its investments in seven critically important products in various stages of preclinical and clinical trials, including the antibodies Vitaxin and Medi-507, and antibodies against each of EphA2, IL-9, PC-Cell-Derived Growth Factor ("PCDGF"), Human

Aspartyl (Asparaginyl) BetaHydroxylase ("HAAH"), and Human Metapneumovirus ("hMPV"), which target, among other illnesses, cancer, asthma and other respiratory diseases, rheumatoid arthritis and psoriasis. These substantial payment obligations to Genentech under the License Agreements, on account of the New Cabilly Patent, harm MedImmune's ability to compete in its sale of antibody products.

Relevant Market

126. The relevant market is the fundamental recombinant DNA technology for producing antibodies, including the process for producing an immunoglobulin or an immunologically functional immunoglobulin fragment in a single host cell that is purportedly covered by the claims of the New Cabilly Patent.

127. This technology, as interpreted by Genentech, is an essential component to the commercial manufacture of monoclonal antibodies. Upon information and belief, there is no known commercially viable method for recombinantly producing therapeutic antibody molecules without this technology, assuming that the New Cabilly Patent is as broad as Genentech says it is. If so, upon information and belief, no known proven alternative to this technology exists currently, and the development of any such alternative would require substantial investment of money, resources and time, and cannot reasonably be expected in the foreseeable future.

128. The relevant geographic market is the entire United States.

Market Effects

129. The unlawful conduct of Genentech and Celltech has required MedImmune and, upon information and belief, other users of this technology to obtain new licenses and/or pay additional and substantial royalties under extant licenses for a term beyond that contemplated under existing patent law, or to be excluded from use of this technology.

130. The unlawful conduct of Genentech and Celltech and the resulting issuance of the New Cabilly Patent has diminished the incentive of MedImmune and other users of the technology to invest in products making use of the technology.

FIRST CAUSE OF ACTION:

DECLARATORY JUDGMENT ON CONTRACTUAL RIGHTS AND OBLIGATIONS

(Against Genentech)

131. MedImmune incorporates the allegations of paragraphs 1 through 130 as if fully set forth herein.

132. An actual controversy has arisen and now exists between the parties concerning the rights and obligations of MedImmune under the terms of the License Agreements. Genentech has demanded that MedImmune make payments under the 1997 License Agreement on the basis that Synagis® would infringe a valid claim of the New Cabilly Patent but for the 1997 License Agreement. MedImmune disputes its obligation to make payments under the 1997 License Agreement because MedImmune's sale of its Synagis® product does not infringe any valid claim of the New Cabilly Patent. The basis for invalidity of the New Cabilly Patent arises under the patent laws of the United States, 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or the judicially created doctrine of obviousness type double patenting.

133. MedImmune hereby seeks a declaratory judgment that it owes no payments under the License Agreements.

SECOND CAUSE OF ACTION:

PATENT INVALIDITY

(Against Genentech and COH)

134. MedImmune incorporates the allegations of paragraphs 1 through 133 as if fully set forth herein.

135. An actual controversy has arisen and now exists between the parties concerning the validity of the New Cabilly Patent.

136. The New Cabilly Patent is invalid because it is anticipated and/or obvious under 35 U.S.C. §§ 102 and/or 103.

137. The New Cabilly Patent is invalid based on the judicially created doctrine of obviousness type double patenting and/or under 35 U.S.C. §§ 101 and/or 103.

138. The New Cabilly Patent is invalid under 35 U.S.C. § 112.

139. MedImmune hereby seeks a declaratory judgment that the New Cabilly Patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or under the judicially created doctrine of obviousness type double patenting:

THIRD CAUSE OF ACTION:

PATENT UNENFORCEABILITY

(Against Genentech and COH)

140. MedImmune incorporates the allegations of paragraphs 1 through 139 as if fully set forth herein.

141. An actual controversy has arisen and now exists between the parties concerning the enforceability of the New Cabilly Patent.

142. Based on the status of Genentech and COH as assignees of the New Cabilly Application and the resulting New Cabilly Patent, Genentech and COH controlled and/or had knowledge of the prosecution of the New Cabilly Application and are both accountable for the material misstatements and omissions made with intent to deceive the PTO. Neither assignee may enforce the New Cabilly Patent if there was inequitable conduct during prosecution.

143. During examination of the New Cabilly Application before a new examiner, while under a duty of candor to the PTO, Genentech and/or COH engaged in inequitable conduct with intent to mislead to PTO in an effort to obtain the New Cabilly Patent.

144. As explained in greater detail above, specifically at paragraphs 48 through 106, the duty of candor was not satisfied by Genentech and/or COH during the examination of the New Cabilly Application.

145. As explained in paragraphs 52 through 78, Genentech and/or COH failed to direct the PTO examiner to potentially significant flaws in the patentability of the claimed invention (*i.e.*, relating to non-enablement) which at least Genentech became aware of no later than during the course of the Civil Action.

146. In particular, Celltech attacked the adequacy of the New Cabilly Application with respect to its teachings relating to antibody "refolding." Genentech, in turn, attacked Celltech's specification as deficient in this respect and then, oddly, asserted that Genenetch's Draft Cabilly Application had the "same information" as that of Celltech's priority document. In short, by Genentech's own admission, its Draft Cabilly Application lacked enabling disclosure of the claimed invention, and Genentech never pointed to any disclosure in its final specification that cured this problem.

147. Genentech and/or COH never directed the PTO to Celltech's attacks on the adequacy of the New Cabilly Application or to Genentech's admissions about the deficiency of its own disclosure.

148. Based on the circumstances described in paragraphs 52-78, and as alleged in paragraphs 66 and 76-77, Genentech and/or COH failed to direct the PTO to these issues that raised doubt as to the patentability of the claims that issued as the New Cabilly Patent with an intent to deceive the PTO.

149. Second, as explained in paragraphs 79 through 91, Genentech and/or COH failed to advise the PTO examiner of Genentech's conclusion that the Vallé prior art reference, involving mRNA, was "functionally equivalent" to the invention claimed by the New Cabilly Patent which expressly claims "DNA," and the fact that Genentech had made a statement in the EPO in 1994 to that effect, contradicting its 1991 position before the PTO.

150. Based on the circumstances described in paragraphs 79-91, and as alleged in paragraph 91, Genentech and/or COH failed to disclose Genentech's contradictory conclusion and statement about the Vallé reference with an intent to deceive to PTO.

151. Third, as explained in paragraphs 92 through 99, Genentech and/or COH "buried" a material prior art reference, the Stanford Application, among more than *275* other dense prior art references, preventing meaningful review of the reference by the examiner.

152. Based on the circumstances described in paragraphs 92-99, and as alleged in paragraphs 95 and 99, Genentech and/or COH buried the Stanford Application with an intent to deceive the PTO.

153. Fourth, as explained in paragraphs 100 through 106, Genentech and/or COH failed to disclose—at all—material pieces of prior art, the Axel Patents.

154. Based on the circumstances described in paragraphs 100-106, and as alleged in paragraph 106, Genentech and/or COH omitted the Axel Patents as references with an intent to deceive the PTO.

155. These incidents of inequitable conduct are all thematically related. Aware of potential patentability flaws exposed no later than the time of the summary judgment briefing in the Civil Action, Genentech orchestrated the

agreement to avoid any PTO examination whatsoever. When the PTO rebuffed that attempt, Genentech turned to misrepresentations and non-disclosures as tools to obtain its patent.

156. As evidenced by the position it took on Vallé before the EPO in 1994, Genentech was well aware that prior work by others involving mRNA could very well make Genentech's DNA claims unpatentable, given that mRNA and DNA are, to use Genentech's words in Europe, "functionally equivalent." Notwithstanding its awareness, Genentech never disclosed its 1994 position to the PTO, leaving the PTO instead with the impression Genentech created in 1991 that the Vallé article was "readily distinguishable" from the claimed invention because it involved mRNA, not DNA.

157. This attempt to downplay Vallé in the PTO makes the burying of the Stanford Application all the more improper—as the Stanford Application teaches the use of DNA.

158. The complete failure to cite the Axel Patents, despite at least Genentech's knowledge of them and payment of royalties on at least two of them, was insidious as well because at least the '216 Patent claimed DNA, not mRNA in the making of an antibody.

159. Thus, on information and belief, Genentech very well knew that it could not distinguish these material pieces of prior art on the same basis it had "distinguished" Vallé—thus it buried one of them and failed to disclose the Axel Patents altogether.

160. The New Cabilly Patent is unenforceable due to Genentech's and/or COH's inequitable conduct before the PTO as set forth above.

161. MedImmune hereby seeks a declaratory judgment that the New Cabilly Patent is unenforceable.

FOURTH CAUSE OF ACTION:

NON-INFRINGEMENT

(Against Genentech and COH)

162. MedImmune incorporates the allegations of paragraphs 1 through 161 as if fully set forth herein.

163. An actual controversy has arisen and now exists between the parties concerning whether MedImmune's Synagis® product infringes any valid and enforceable claim of the New Cabilly Patent, but for the 1997 License Agreement.

164. MedImmune hereby seeks a declaratory judgment that, but for the 1997 License Agreement, its Synagis® product does not infringe any valid and enforceable claim of the New Cabilly Patent.

FIFTH CAUSE OF ACTION:

SECTION 1 OF THE SHERMAN ACT

(Against Genentech and Celltech)

165. MedImmune incorporates the allegations of paragraphs 1 through 164 as if fully set forth herein.

166. Genentech and Celltech conspired and reached the collusive Agreement that ultimately led to the improper issuance of the New Cabilly Patent.

167. Upon information and belief, the Agreement was entered into with the bad faith intent to harm competition.

168. The Agreement has a direct effect upon interstate trade or commerce.

169. Due to Genentech's and Celltech's anticompetitive behavior, MedImmune among others in the industry, has been harmed by either being blocked from the market altogether or by being required to make exorbitant payments for use of the

technology purportedly covered by the claims of the New Cabilly Patent.

170. The unlawful contract, combination, or conspiracy of Genentech and Celltech has no legitimate business objective and is a *per se* violation of Section 1 of the Sherman Act, 15 U.S.C. 1, *et seq.*

171. Upon information and belief, among other things, the Agreement is a market allocation agreement between horizontal competitors that is anticompetitive and illegal *per se* under Section 1 of the Sherman Act, 15 U.S.C. 1, *et seq.*

172. Alternatively, the unlawful contract, combination, or conspiracy of Genentech and Celltech unreasonably restrains competition in the relevant market and violates Section 1 of the Sherman Act under the Rule of Reason.

173. Genentech and Celltech are liable under Section 1 of the Sherman Act to MedImmune for damages in an amount to be proven at trial, including, without limitation, all payments made by MedImmune to Genentech on account of the New Cabilly Patent; which damages should be trebled under 15 U.S.C. § 15(a), plus interest, costs and expenses, including attorney fees.

SIXTH CAUSE OF ACTION:

SECTION 2 OF THE SHERMAN ACT (CONSPIRACY TO MONOPOLIZE)

(Against Genentech and Celltech)

174. MedImmune incorporates the allegations of paragraphs 1 through 173 as if fully set forth herein.

175. Genentech and Celltech conspired and reached the collusive Agreement that ultimately led to the improper issuance of the New Cabilly Patent.

176. Upon information and belief, the Agreement was entered into with the specific intent to grant a monopoly to Genentech that consists of the exclusive rights to what is asserted to be the fundamental technology embodied in the New Cabilly Patent.

177. The Agreement has a direct effect upon interstate trade or commerce.

178. Due to Genentech's and Celltech's anticompetitive behavior, MedImmune, among others in the industry, has been harmed by either being blocked from the market altogether or by being required to make exorbitant payments for use of the technology purportedly covered by the claims of the New Cabilly Patent.

179. The unlawful conspiracy of Genentech and Celltech violates Section 2 of the Sherman Act, 15 U.S.C. § 2, *et seq.*

180. Genentech and Celltech are liable under Section 2 of the Sherman Act to MedImmune for damages in an amount to be proven at trial, including, without limitation, all payments made by MedImmune to Genentech on account of the New Cabilly Patent; which damages should be trebled under 15 U.S.C. § 15(a), plus interest, costs and expenses, including attorney fees.

SEVENTH CAUSE OF ACTION:

SECTION 2 OF THE SHERMAN ACT (MONOPOLIZATION BY GENENTECH)

(Against Genentech)

181. MedImmune incorporates the allegations of paragraphs 1 through 180 as if fully set forth herein.

182. Upon information and belief, Genentech has monopoly power in the relevant market (as defined above).

183. Upon information and belief, Genentech willfully acquired and/or maintained its market dominance in the relevant market by anticompetitive means.

184. Genentech's willful acquisition and/or maintenance of its monopoly power by anticompetitive means has harmed MedImmune, among others in the industry, by either blocking them from the market altogether or requiring them to make exorbitant payments for use of the technology.

185. Genentech is liable under Section 2 of the Sherman Act to MedImmune for damages in an amount to be proven at trial, including, without limitation, all payments made to date by MedImmune to Genentech on account of the New Cabilly Patent; which damages should be trebled under 15 U.S.C. § 15(a), plus interest, costs and expenses, including attorney fees.

EIGHTH CAUSE OF ACTION:

THE CARTWRIGHT ACT
(UNLAWFUL RESTRAINT OF TRADE)

(Against Genentech and Celltech)

186. MedImmune incorporates the allegations of paragraphs 1 through 185 as if fully set forth herein.

187. Genentech and Celltech improperly conspired and reached the collusive Agreement that ultimately led to the improper issuance of the New Cabilly Patent.

188. Upon information and belief, the Agreement was entered into with the bad faith intent to harm competition.

189. The Agreement has a direct effect upon trade or commerce in California.

190. The collusive Agreement has no legitimate pro-competitive business objective and unreasonably harms competition.

191. Due to Genentech's and Celltech's anticompetitive behavior in violation of Section 16720 of the California Cartwright Act, MedImmune has been damaged by, for example, being required to make exorbitant payments for use of the New Cabilly Patent technology. Genentech and Celltech are liable to MedImmune for damages in an amount to be proven at trial; trebled under § 16750, plus interest, costs and expenses, including attorney fees.

NINTH CAUSE OF ACTION:

THE CARTWRIGHT ACT
(CONSPIRACY TO MONOPOLIZE)

(Against Genentech and Celltech)

192. MedImmune incorporates the allegations of paragraphs 1 through 191 as if fully set forth herein.

193. Genentech and Celltech conspired and reached the collusive Agreement that ultimately led to the improper issuance of the New Cabilly Patent.

194. Upon information and belief, the Agreement was entered into with the specific intent to grant a monopoly to Genentech that consists of the exclusive rights to what is asserted to be the fundamental technology embodied in the New Cabilly Patent.

195. The Agreement has a direct effect upon trade or commerce in California.

196. Due to Genentech's and Celltech's anticompetitive behavior, MedImmune, among others in the industry, has been harmed by either being blocked from the market altogether or by being required to make exorbitant payments for use of the technology purportedly covered by the claims of the New Cabilly Patent.

197. The unlawful conspiracy of Genentech and Celltech violates Sections 16720 *et seq.* of the California Cartwright Act.

198. Genentech and Celltech are liable under Section 16720 of the Cartwright Act to MedImmune for damages in an amount to be proven at trial, including, without limitation, all payments made to date by MedImmune to Genentech on account of the New Cabilly Patent; which damages should be trebled under § 16720, plus interest, costs and expenses, including attorney fees.

TENTH CAUSE OF ACTION:

SECTION 17200 OF THE CALIFORNIA BUSINESS & PROFESSIONS CODE

(Against Genentech and Celltech)

199. MedImmune incorporates the allegations of paragraphs 1 through 198 as if fully set forth herein.

200. Upon information and belief, Genentech and Celltech have colluded to obtain the issuance of the New Cabilly Patent, and have engaged in unfair, illegal or fraudulent business practices in violation of Section 17200 of the California Business & Professions Code. Due to the Defendants' unfair business practices, MedImmune has been required to make exorbitant payments for use of the New Cabilly Patent's technology.

201. Genentech and Celltech are liable to MedImmune for restitution of payments made to Genentech on account of the New Cabilly Patent, which payments are continuing, and Genentech should be enjoined from attempting to enforce the New Cabilly Patent and any of the terms of the collusive Agreement.

PRAYER FOR RELIEF

WHEREFORE, plaintiff MedImmune requests that judgment be entered in favor of MedImmune and against Defendants:

1. DECLARING that MedImmune has no obligation to pay royalties to Genentech under the License Agreements because the New Cabilly Patent is invalid and/or unenforceable and/or because MedImmune's sale of its Synagis® product does not infringe any valid claim of the New Cabilly Patent;

2. DECLARING that the New Cabilly Patent is invalid under 35 U.S.C. §§ 101, 102, 103, 112, *et seq.* and/or the judicially created doctrine of obviousness type double patenting;

3. DECLARING that MedImmune's sale of its Synagis® product does not infringe any valid and enforceable claim of the New Cabilly Patent;

4. DECLARING that the Agreement between Genentech and Celltech violates Section 1 of the Sherman Act;

5. DECLARING that the Agreement between Genentech and Celltech violates Section 2 of the Sherman Act;

6. DECLARING that the Agreement between Genentech and Celltech violates Section 17200 of the California Business & Professions Code;

7. DECLARING that the Agreement between Genentech and Celltech violates Section 16720 of the Cartwright Act;

8. ENJOINING Genentech and/or COH from enforcing the New Cabilly Patent;

9. AWARDING MedImmune actual and exemplary damages resulting from Genentech's and Celltech's anticompetitive use of the New Cabilly Patent, including, without limitation, treble damages under 15 U.S.C. § 15(a), Section

16750 of the California Cartwright Act, and such other exemplary damages as are available at law, including those available on account of Genentech's and Celltech's oppression, fraud, or malice; attorney fees; and costs; and

10. PROVIDING MedImmune such other and further relief as the Court may deem just and proper under the circumstances.

Dated: August 13, 2003

DEWEY BALLANTINE LLP

By: /s/ Jeffrey R. Witham
JEFFREY R. WITHAM
Attorneys for Plaintiff MEDIMMUNE, INC.

DEMAND FOR JURY TRIAL

Plaintiff MedImmune, Inc. hereby demands a jury trial as provided by Rule 38(a) of the Federal Rules of Civil Procedure.

DEWEY BALLANTINE LLP

By: /s/ Jeffrey R. Witham
JEFFREY R. WITHAM
Attorneys for Plaintiff MEDIMMUNE, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CASE NO. CV03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

DEFENDANT GENENTECH, INC.'s ANSWER AND AFFIRMATIVE DEFENSES

DEMAND FOR JURY TRIAL

Defendant Genentech, Inc. ("Genentech"), by its attorneys, hereby provides the following answer to the First Amended Complaint in this matter. Genentech notes that many of the allegations contained in the First Amended Complaint include false premises or assumptions and lack foundation. Thus, a denial of an allegation should be construed herein as a denial of the allegation itself, as well as any of its underlying and unsupported assumptions.

JURISDICTION AND VENUE

1. Genentech admits that MedImmune, Inc. ("MedImmune") purports to seek declaratory relief pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §§ 2201 and 2202. Genentech admits that, based on the allegations, the Court has jurisdiction to hear this dispute, but denies that MedImmune is entitled to any relief or recovery whatsoever.

2. Genentech admits the allegation in paragraph 2.

THE PARTIES

3. Genentech admits that MedImmune, by and through its attorneys, purports to bring this action under antitrust, patent, and unfair competition laws against defendants Genentech, City of Hope ("COH"), and Celltech R&D Ltd. ("Celltech") (collectively, "Defendants") and that MedImmune purports to seek declaratory relief. Genentech denies that it engaged in any unlawful or improper conduct and denies that MedImmune is entitled to any relief or recovery whatsoever.

4. Genentech lacks sufficient information to answer the allegations in paragraph 4 and, on that basis, denies them.

5. Genentech admits that MedImmune sells a product under the name Synagis®. Genentech lacks sufficient information to answer the remaining allegations in paragraph 5 and, on that basis, denies them.

6. Genentech admits the allegations in paragraph 6.

7. Genentech admits on information and belief that COH is a California non-for-profit organization with its principal place of operation in Duarte, California. Genentech admits that COH is a co-assignee of the patent at issue in this case.

8. Genentech admits on information and belief that Celltech is a British company with its principal place of business in Slough, England. Genentech lacks sufficient information to answer the remaining allegations in paragraph 8 and, on that basis, denies them.

SUMMARY OF THIS ACTION

9. Genentech admits that MedImmune has purportedly filed this action to challenge an agreement between Genentech and Celltech and that MedImmune purports to seek declaratory relief. Genentech admits that it is a biotechnology company. Genentech admits that MedImmune purports to define "Agreement" in the manner alleged in paragraph 9 as

"an illegal and anticompetitive agreement." Genentech denies that it has entered into "an illegal and anticompetitive agreement" and denies that it engaged in any unlawful or improper conduct. Genentech further denies that MedImmune is entitled to the declaration it seeks or any other relief or recovery whatsoever. Genentech denies the remaining allegations in paragraph 9.

10. Genentech admits that it entered into certain agreements with Celltech to settle the case captioned *Genentech, Inc v. Celltech Therapeutics, Ltd.*, Case No. C-98-3926 MMC ("Civil Action") in the United States District Court for the Northern District of California, and to license certain rights to Celltech under U.S. Patent No. 6,331,415 B1 (the "'415 Patent"). Genentech further admits that the details of those agreements are confidential. Genentech denies the remaining allegations in paragraph 10.

11. Genentech admits that it was involved in a patent interference relating to U.S. Patent No. 4,816,397 (the "Boss Patent") and U.S. Patent Application No. 07/205,419 (the "'415 Patent Application"). Genentech admits that in the patent interference, it asserted that its assignors invented the same subject matter claimed by the Boss Patent before Celltech's assignors. Genentech admits that in the patent interference proceeding before the Patent and Trademark Office (Interference No. 102,572), the Board of Patent Appeals and Interferences ("PTO Board") ruled (incorrectly) in favor of Celltech regarding priority of invention. Genentech admits that it then filed the Civil Action pursuant to 35 U.S.C. § 146 to obtain judicial review of the PTO Board's ruling. Genentech admits that Judge Maxine M. Chesney denied two of Genentech's motions for summary adjudication in the Civil Action after concluding that there were triable issues of material fact. Genentech admits that, following Judge Chesney's suggestion that the parties resolve their dispute prior to trial, it entered into certain agreements with Celltech to settle

the Civil Action relating to the Boss Patent and the '415 Patent Application. Genentech denies the remaining allegations in paragraph 11.

12. Genentech admits that, prior to March 16, 2001, it entered into certain agreements with Celltech to settle legal proceedings relating to the Boss Patent and the '415 Patent Application, and asserts that these agreements speak for themselves. Genentech denies the remaining allegations in paragraph 12.

13. Genentech denies the allegations in paragraph 13 as they relate to it. Genentech lacks sufficient knowledge or information to admit or deny the allegations in paragraph 13 as they relate to Celltech and, on that basis, denies them.

14. Genentech denies the allegations in paragraph 14.

15. To the extent that this paragraph is deemed to relate to Celltech or other third parties, Genentech is without sufficient information to answer the allegations in paragraph 15 and, on that basis, denies them. To the extent that the paragraph relates to Genentech, Genentech denies the allegations in paragraph 15.

16. Genentech lacks sufficient information to answer the allegations in the first sentence in paragraph 16 and, on that basis, denies them. Genentech denies the allegations in the second sentence in paragraph 16.

17. Genentech admits that the term of the '415 Patent will expire in 2018. To the extent that this paragraph is deemed to relate to Celltech, Genentech is without sufficient information to answer the allegations in paragraph 17 and, on that basis, denies them. To the extent that the paragraph relates to Genentech, Genentech denies the allegations in paragraph 17.

18. Genentech admits that MedImmune has made payments to Genentech under a license agreement entered into between MedImmune and Genentech on or about June 5,

1997 ("1997 License Agreement"). Genentech admits that the 1997 License Agreement provided rights to various intellectual property, including the patent application that later matured into the '415 Patent. Genentech admits that Genentech and MedImmune entered into license agreements on or about February 7, 2003, that cover products that MedImmune has stated it is developing. Genentech denies the remaining allegations in paragraph 18.

19. Genentech admits that the First Amended Complaint purports to state claims under the cited statutes and legal theories. Genentech denies that it engaged in any unlawful or improper conduct and denies that MedImmune is entitled to any recovery whatsoever.

20. Genentech admits that the First Amended Complaint purports to seek declaratory relief. Genentech denies that it engaged in any unlawful or improper conduct denies that MedImmune is entitled to the declaration it seeks, or to any relief whatsoever.

21. Genentech admits that on April 8, 1983, a patent application listing Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel as inventors was filed in the United States Patent and Trademark Office. Genentech admits that application was given U.S. Patent Application Serial No. 06/483,457. Genentech admits that Messrs. Heynecker, Holmes, and Wetzel were affiliated with Genentech, and is informed and believes that Messrs. Cabilly and Riggs were affiliated with COH. Genentech further admits that Genentech and COH are co-assignees of both U.S. Patent No. 4,816,567 (the "'567 Patent") as well as the '415 Patent.

22. Genentech admits that the '567 Patent was issued on March 28, 1989, based on Patent Application Serial No. 06/483,457.

23. Genentech admits that on June 10, 1988, a continuation of U.S. Patent Application Serial No. 06/483,457 was filed, and that the continuation application was assigned US. Patent Application Serial No. 07/205,419.

24. Genentech admits that the PTO issued both the '567 Patent and U.S. Patent No. 4,816,397 on the same day, March 28, 1989.

25. Genentech admits that after the Boss Patent issued, Genentech amended U.S. Patent Application Serial No. 07/205,419 to copy claims from the Boss Patent to provoke an interference, based on the fact that Messrs. Cabilly, Heyneker, Holmes, Riggs, and Wetzel were the first inventors of the subject matter therein. Genentech admits that the PTO Board declared an interference between the Boss Patent and U.S. Patent Application Serial No. 07/205,419. Genentech denies the remaining allegations in paragraph 25.

26. Genentech admits that on February 28, 1991, the PTO Board declared Patent Interference No. 102,572 between certain claims of U.S. Patent Application Serial No. 07/205,419 and the claims of the Boss Patent. Genentech denies the remaining allegations in paragraph 26.

27. Genentech admits that the PTO Board declared Patent Interference No. 102,572 on February 28, 1991 and that the Board issued a final decision on August 13, 1998. Genentech admits that Genentech and Celltech made arguments to the Board regarding priority of invention. Genentech denies the remaining allegations in paragraph 27.

28. Genentech admits that on August 13, 1998, the PTO Board issued a final decision in Patent Interference No. 102,572 and refers to the decision for its terms. Genentech denies the remaining allegations in paragraph 28.

29. Genentech admits that on October 9, 1998, it commenced the Civil Action in order to obtain judicial review of the PTO Board's incorrect decision.

30. Genentech admits that the Civil Action was filed on October 9, 1998 and judgment was entered by the district court on March 16, 2001. Genentech admits that the Civil Action included depositions, document production, and expert disclosures.

31. Genentech admits that, during the course of the Civil Action, Dr. Cabilly located the draft patent application dated February 25, 1983. Genentech admits that Genentech made certain contentions regarding the draft patent application, including statements made in Genentech's summary adjudication papers filed in the Civil Action, and subject to any applicable protective order, refers to Genentech's motion papers for their content. Genentech denies the remaining allegations in paragraph 31.

32. Genentech admits that it moved for summary adjudication in the Civil Action and, subject to any applicable protective order, refers to Genentech's motion papers for their content. Genentech denies the remaining allegations in paragraph 32.

33. Genentech admits that Celltech opposed Genentech's motions for summary adjudication in the Civil Action, and, subject to any applicable protective order, refers to Celltech's motion papers for their content. Genentech denies the remaining allegations in paragraph 33.

34. Genentech admits that it filed reply briefs in support of its motions for summary adjudication, and, subject to any applicable protective order, refers to Genentech's reply briefs for their content. Genentech admits that Genentech filed a motion for summary adjudication that Celltech was not entitled to priority to the March 25, 1983 filing date of the British Boss patent application, and, subject to any applicable protective order, refers to Genentech's motion papers for their content. Genentech denies the remaining allegations in paragraph 34.

35. Genentech admits that it filed summary adjudication motions in the Civil Action, and that both it and Celltech filed papers in connection therewith, and, subject to any applicable protective order, refers to the motion papers for their content. Genentech denies the remaining allegations in paragraph 35.

36. Genentech admits that it entered into certain agreements with Celltech to settle the Civil Action after the district court denied Genentech's motions for summary adjudication on July 31, 2000. Genentech denies the remaining allegations in paragraph 36, and further denies that it engaged in any unlawful or improper conduct.

37. Genentech denies the allegations in paragraph 37, and further denies that it engaged in any unlawful or improper conduct.

38. To the extent that this paragraph is deemed to relate to Celltech, Genentech is without sufficient information to answer the allegations in paragraph 38 and, on that basis, denies them. To the extent that the paragraph relates to Genentech, Genentech denies the allegations in paragraph 38, and further denies that it engaged in any unlawful or improper conduct.

39. Genentech admits that in connection with their settlement agreement in the Civil Action, Genentech and Celltech submitted a proposed order to the District Court, and that the proposed order contained several proposed findings of fact and conclusions of law, including a proposed finding that "Genentech is entitled as a matter of law to priority over Celltech to invention described by the count." Genentech admits that Celltech opposed Genentech's motions for summary adjudication in the Civil Action, and, subject to any applicable protective order, refers to Celltech's motion papers for their content. Genentech denies the remaining allegations in paragraph 39.

40. Genentech denies the allegations in paragraph 40.

41. Genentech admits that Genentech and Celltech submitted a proposed order to the District Court and that the District Court signed an Order on March 16, 2001, and refers to the proposed order and Order for its content. Genentech denies the remaining allegations in paragraph 41, and further denies that it engaged in any unlawful or improper conduct.

42. Genentech admits that Genentech and Celltech submitted a proposed order to the District Court and that the District Court signed an Order on March 16, 2001, and refers to the proposed order and Order for its content.

43. Genentech admits that, following entry of the District Court's Judgment, the PTO Board issued a Final Order After District Court Judgment, and refers to the Final Order for its terms.

44. Genentech denies the allegations in paragraph 44, and further denies that it engaged in any unlawful or improper conduct.

45. Genentech admits that the PTO Board's Final Order After District Court Judgment contains a footnote which reads: "We will note that if a patent is issued to Cabilly, its term will begin to run now and the public has already been subject to patent rights of Boss since 1989, and that the interference has been pending since 1991." Genentech denies the remaining allegations in paragraph 45.

46. Genentech admits that the PTO Board issued a Final Order After District Court Judgment, and refers to the Final Order for its terms. Genentech denies the remaining allegations in paragraph 46.

47. Genentech admits that Celltech commenced a civil action captioned *Celltech R&D Ltd. v. Genentech, Inc.*, in the United States District Court for the Northern District of California pursuant to 35 U.S.C. § 146. To the extent that this paragraph is deemed to relate to Celltech, Genentech is

without sufficient information to answer the allegations in paragraph 47 and, on that basis, denies them. To the extent that the paragraph relates to Genentech, Genentech denies the remaining allegations in paragraph 47.

48. Genentech admits that the PTO Board ordered that the '415 Patent Application be forwarded to the patent examiner. Genentech denies the remaining allegations in paragraph 48.

49. Genentech denies the allegations in paragraph 49.

50. Genentech admits that after the PTO Board issued the Final Order After District Court Judgment, it ordered that the '415 Patent Application be forwarded to the patent examiner. Genentech denies the remaining allegations in paragraph 50.

51. Genentech denies the allegations in paragraph 51.

52. Genentech denies the allegations in paragraph 52.

53. Genentech admits that Celltech opposed Genentech's Motion for Summary Adjudication that Genentech Conceived of the Invention Described by the Count before March 25, 1983 in the Civil Action, and, subject to any applicable protective order, refers to Celltech's motion papers for their content. Genentech denies the remaining allegations in paragraph 53.

54. Genentech admits that Celltech opposed Genentech's Motion for Summary Adjudication that Genentech Conceived of the Invention Described by the Count before March 25, 1983 in the Civil Action, and, subject to any applicable protective order, refers to Celltech's motion papers for their content. Genentech denies the remaining allegations in paragraph 54.

55. Genentech admits that in the Civil Action it produced the Draft '415 Patent Application and, subject to any applicable protective order, refers to the Draft '415 Patent Application for its content. Genentech denies the remaining allegations of paragraph 55.

56. Genentech denies the allegations in paragraph 56.

57. Genentech admits that it filed a Motion for Summary Adjudication that Genentech Conceived of the Invention Described by the Count before March 25, 1983 in the Civil Action, and, subject to any applicable protective order, refers to Genentech's motion papers for their content. Genentech denies the remaining allegations in paragraph 57.

58. Genentech admits that it filed summary adjudication motions in the Civil Action and that Celltech opposed Genentech's motions for summary adjudication, and, subject to any applicable protective order, refers to Genentech's and Celltech's motion papers for their content. Genentech denies the remaining allegations in paragraph 58.

59. Genentech admits that it took a deposition of Dr. Weissman in the Civil Action and, subject to any applicable protective order, refers to the deposition transcript for its content. Genentech denies the remaining allegations in paragraph 59.

60. Genentech admits that it filed a Motion for Summary Adjudication that Celltech is Not Entitled to a Priority Date Based on its British Patent Application in the Civil Action, and, subject to any applicable protective order, refers to that motion for its content. Genentech denies the remaining allegations in paragraph 60.

61. Genentech admits that it filed a reply brief in support of its Motion for Summary Adjudication that Genentech Conceived of the Invention Described by the Count before March 25, 1983 and a Motion for Summary Adjudication that Celltech is Not Entitled to a Priority Date Based on its British Patent Application, and, subject to any applicable protective order, refers to those motion papers for their content. Genentech denies the remaining allegations in paragraph 61.

62. Genentech admits that it filed a Motion for Summary Adjudication that Genentech Conceived of the Invention Described by the Count before March 25, 1983 and a Motion for Summary Adjudication that Celltech is Not Entitled to a Priority Date Based on its British Patent Application, and, subject to any applicable protective order, refers to those motion papers for their content. Genentech denies the remaining allegations in paragraph 62.

63. Genentech admits that it filed a Motion for Summary Adjudication that Genentech Conceived of the Invention Described by the Count before March 25, 1983 and a Motion for Summary Adjudication that Celltech is Not Entitled to a Priority Date Based on its British Patent Application, and, subject to any applicable protective order, refers to those motion papers for their content. Genentech denies the remaining allegations in paragraph 63.

64. Genentech denies the allegations in paragraph 64, and further denies that it engaged in any unlawful or improper conduct.

65. Genentech denies the allegations in paragraph 65.

66. Genentech denies the allegations in paragraph 66, and further denies that it engaged in any unlawful or improper conduct.

67. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 67. Genentech denies that it engaged in any unlawful or improper conduct.

68. Genentech denies the allegations in paragraph 68, and further denies that it engaged in any unlawful or improper conduct.

69. Genentech denies the allegations in paragraph 69, and further denies that it engaged in any unlawful or improper conduct.

70. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 70.

71. Genentech admits that the District Court signed an Order on March 16, 2001, and refers to the Order for its content. Genentech further admits that, following entry of the District Court's Judgment, the PTO Board issued a Final Order After District Court Judgment, and refers to the Final Order for its terms. Genentech denies the remaining allegations in paragraph 71.

72. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of Paragraph 72.

73. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 73.

74. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 74.

75. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 75.

76. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 76.

77. Genentech denies the allegations in paragraph 77, and further denies that it engaged in any unlawful or improper conduct.

78. Genentech denies the allegations in paragraph 78, and further denies that it engaged in any unlawful or improper conduct.

79. Genentech denies the allegations in paragraph 79, and further denies that it engaged in any unlawful or improper conduct.

80. Genentech admits that it filed an Information Disclosure Statement ("IDS") dated September 18, 1991 with the PTO and refers to the IDS for its contents.

81. Genentech admits that it filed an IDS dated September 18, 1991 with the PTO, and refers to the IDS for its contents.

82. Genentech admits that it filed a paper in an April 19, 1994 Notice of Opposition proceeding (EP-B-0120694) before the European Patent Office, and, subject to any applicable protective order, refers to the paper for its contents. Genentech denies the remaining allegations in paragraph 82.

83. Genentech admits that it filed a paper in an April 19, 1994 Notice of Opposition proceeding (EP-B-0120694) before the European Patent Office, and, subject to any applicable protective order, refers to the paper for its contents. Genentech denies the remaining allegations in paragraph 83.

84. Genentech admits that it filed a paper in an April 19, 1994 Notice of Opposition proceeding (EP-B-0120694) before the European Patent Office, and, subject to any applicable protective order, refers to the paper for its contents. Genentech denies the remaining allegations in paragraph 84.

85. Genentech admits that it filed a paper in an April 19, 1994 Notice of Opposition proceeding (EP-B-0120694) before the European Patent Office, and, subject to any applicable protective order, refers to the paper for its contents.

Genentech further admits that it filed an IDS dated September 18, 1991 with the PTO, and refers to the IDS for its contents. Genentech denies the remaining allegations in paragraph 85.

86. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 86.

87. Genentech admits that the PTO Board issued a Final Order After District Court Judgment, and refers to the Final Order for its terms. Genentech admits that the PTO Board ordered that the '415 Patent Application be forwarded to the patent examiner. Genentech denies the remaining allegations in paragraph 87.

88. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 88.

89. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 89.

90. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 90.

91. Genentech denies the allegations in paragraph 91, and further denies that it engaged in any unlawful or improper conduct.

92. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 92.

93. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 93.

94. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 94.

95. Genentech denies the allegations in paragraph 95, and further denies that it engaged in any unlawful or improper conduct.

96. Genentech admits that it properly filed an IDS dated September 13, 2001, and refers to the IDS for its contents. Genentech denies the remaining allegations in paragraph 96, and further denies that it engaged in any unlawful or improper conduct.

97. Genentech admits that it filed an IDS dated September 13, 2001, and refers to the IDS for its contents. Genentech denies the remaining allegations in paragraph 97.

98. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 98.

99. Genentech denies the allegations in paragraph 99, and further denies that it engaged in any unlawful or improper conduct.

100. Genentech denies the allegations in paragraph 100, and further denies that it engaged in any unlawful or improper conduct.

101. Genentech denies the allegations in paragraph 101.

102. Genentech admits that it filed a complaint in the civil action captioned *Genentech, Inc. v. The Trustees of Columbia*

University of the City of New York, Case No. C 03-1603 VRW, in the United States District Court for the Northern District of California, and refers to the complaint for its contents. Genentech denies the remaining allegations in paragraph 102.

103. Genentech denies the allegations in paragraph 103.

104. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 104.

105. The prosecution history of the '415 Patent and documents therein speak for themselves. GNE denies that there was a failure to meet any obligations or duties that apply and further denies any other allegations of paragraph 105.

106. Genentech denies the allegations in paragraph 106, and further denies that it engaged in any unlawful or improper conduct.

107. Genentech admits that the '415 Patent issued on December 18, 2001. Genentech denies the remaining allegations in paragraph 107, and further denies that it engaged in any unlawful or improper conduct

108. Genentech admits the allegations in paragraph 108.

109. Genentech admits that the '415 Patent, in the abstract of the invention, contains the language: "processes for producing an immunoglobulin or an immunologically functional immunoglobulin fragment containing at least the variable domains of the immunoglobulin heavy and light chains. The processes can use on one or more vectors which produce both the heavy and light chains or fragments thereof in a single cell." Genentech further admits that one of its press releases states that the '415 Patent relates to "fundamental methods and compositions used to produce antibodies by recombinant

DNA technology," and that certain such antibody molecules can be used to provide beneficial treatment for certain illnesses.

110. To the extent that this paragraph is deemed to relate to Celltech, Genentech is without sufficient information to answer the allegations in paragraph 110 and, on that basis, denies them. To the extent that the paragraph relates to Genentech, Genentech denies the allegations in paragraph 110.

111. To the extent that this paragraph is deemed to relate to Celltech, Genentech is without sufficient information to answer the allegations in paragraph 111 and, on that basis, denies them. To the extent that the paragraph relates to Genentech, Genentech denies the allegations in paragraph 111.

112. Genentech admits that Genentech and Celltech properly filed their settlement agreement with the PTO under seal pursuant to applicable PTO rules and procedures. Genentech denies the remaining allegations in paragraph 112, and further denies that it engaged in any unlawful or improper conduct.

113. Genentech admits that, in a letter dated February 13, 2002, MedImmune requested a copy of Genentech and Celltech's agreement to settle the Civil Action. Genentech denies the remaining allegations in paragraph 113.

114. Genentech admits that, in a letter dated March 24, 2002, it responded to MedImmune's request for a copy of Genentech and Celltech's agreement to settle the Civil Action, and stated that: "The settlement agreement is a confidential document, and we cannot provide it to you." Genentech denies the remaining allegations in paragraph 114.

115. Genentech admits that, on May 8, 2002, MedImmune petitioned the PTO for access to the settlement agreement

between Celltech and Genentech in the Civil Action. Genentech admits that Genentech and Celltech opposed that petition. Genentech admits that the PTO denied MedImmune's petition. Genentech denies the remaining allegations in paragraph 115.

116. Genentech admits that various statements regarding the '415 Patent have been attributed to Genentech employees. Genentech further admits that the '415 Patent covers methods that come within its literal scope and are within the doctrine of equivalents as properly applied. Genentech denies the remaining allegations in paragraph 116.

117. Genentech admits that, in a letter dated January 7, 2002, Genentech confirmed to MedImmune its "expectation that MedImmune will pay royalties on sales of its Synagis antibody product pursuant to the license granted by Genentech under the recently issued U.S. Patent No. 6,331,415." Genentech denies any remaining allegations in paragraph 117.

118. Genentech admits that, in a letter dated February 13, 2002, MedImmune requested that Genentech advise it of Genentech's "basis for believing that MedImmune's product would infringe any valid claim of the '415 Patent such that royalties would be due." Genentech admits that, in that letter, MedImmune requested a copy of Genentech and Celltech's agreement to settle the Civil Action. Genentech denies the remaining allegations in paragraph 118.

119. Genentech admits that MedImmune "made the requested royalty payment" under the 1997 License Agreement and that, by letter dated March 8, 2002, MedImmune stated that "[s]uch payment, however, was made under protest and with reservation of all of our rights." Genentech admits that MedImmune continues to make royalty payments under the 1997 License Agreement on a quarterly basis. Genentech lacks sufficient information to answer the remaining allegations in paragraph 119 and, on that basis, denies them.

120. Genentech denies the allegations in paragraph 120.

121. Genentech admits that Celltech owned the Boss Patent. Genentech lacks sufficient information to answer the remaining allegations in paragraph 121 and, on that basis, denies them.

122. Genentech lacks sufficient information to answer the allegations in paragraph 122 and, on that basis, denies them.

123. To the extent that this paragraph is deemed to relate to Celltech, Genentech is without sufficient information to answer the allegations in paragraph 123 and, on that basis, denies them. To the extent that the paragraph relates to Genentech, Genentech admits that the '415 Patent will expire in 2018. Genentech denies the remaining allegations in paragraph 123.

124. To the extent that this paragraph is deemed to relate to Celltech, Genentech is without sufficient information to answer the allegations in paragraph 124 and, on that basis, denies them. To the extent that the paragraph relates to Genentech, Genentech admits that companies that wish to license the '415 Patent may do so and that, without a license, such companies are subject to U.S. Patent laws and thus not free to practice the claims of the '415 Patent as provided by those laws. Genentech denies the remaining allegations in paragraph 124.

125. To the extent that this paragraph is deemed to relate to Celltech, Genentech is without sufficient information to answer the allegations in paragraph 125 and, on that basis, denies them. Genentech admits that it entered into license agreements with MedImmune in 2003 under the '415 Patent to cover Vitaxin, Medi-507, and antibodies against Eph A2, IL-9, PC-Cell-Derived Growth Factor ("PCDGF"), Human Aspartyl (Asparaginyl) BetaHydroxylase ("HAAH"), and Human Metapneumovirus ("hMPV"). Genentech further admits that MedImmune has made payments to Genentech

under the 1997 License Agreement for certain sales of Synagis®. These payments were made, and the 2003 license agreements entered into, because MedImmune chose to practice one or more claims of the '415 Patent. Genentech denies the remaining allegations in paragraph 125.

126. Genentech does not understand this allegation and, on that basis, denies it.

127. Genentech is without sufficient information to form a belief as to the truth of the allegations in paragraph 127 and, on that basis, denies them.

128. Inasmuch as the allegations in paragraph 128 purport to state legal conclusions, no response thereto is required. To the extent a response is required, Genentech denies the allegations in paragraph 128.

129. Genentech denies the allegations in paragraph 129, and further denies that it engaged in any unlawful or improper conduct.

130. Genentech denies the allegations in paragraph 130, and further denies that it engaged in any unlawful or improper conduct.

FIRST CAUSE OF ACTION

DECLARATORY JUDGMENT ON

CONTRACTUAL RIGHTS AND OBLIGATIONS

(Against Genentech)

131. Genentech repeats and realleges its answers to paragraphs 1 through 130 above.

132. Inasmuch as the averments of paragraph 132 purport to state legal conclusions, no response thereto is required. Genentech denies that MedImmune is entitled to the relief it seeks, or to any relief, and further denies the remaining allegations in paragraph 132.

133. Genentech admits that MedImmune purports to seek declaratory relief, but denies that MedImmune is entitled to a declaratory judgment, or to any relief whatsoever.

SECOND CAUSE OF ACTION

PATENT INVALIDITY

(Against Genentech and COH)

134. Genentech repeats and realleges its answers to paragraphs 1 through 133 above.

135. Inasmuch as the averments of paragraph 135 purport to state legal conclusions, no response thereto is required. Genentech denies that MedImmune is entitled to the relief it seeks, or to any relief and further denies the remaining allegations in paragraph 135.

136. Genentech denies the allegations in paragraph 136.

137. Genentech denies the allegations in paragraph 137.

138. Genentech denies the allegations in paragraph 138.

139. Genentech admits that MedImmune purports to seek declaratory relief but denies that MedImmune is entitled to a declaratory judgment, or to any relief whatsoever.

THIRD CAUSE OF ACTION

PATENT UNENFORCEABILITY

(Against Genentech and COH)

140. Genentech repeats and realleges its answers to paragraphs 1 through 139 above.

141. Inasmuch as the averments of paragraph 141 purport to state legal conclusions, no response thereto is required. Genentech denies that MedImmune is entitled to the relief it seeks, or to any relief, and further denies the remaining allegations in paragraph 141.

142. Genentech denies the allegations in paragraph 142.

143. Genentech denies the allegations in paragraph 143, and further denies that it engaged in any unlawful or improper conduct.

144. Genentech denies the allegations in paragraph 144, and further denies that it engaged in any unlawful or improper conduct.

145. Genentech refers to and incorporates its answers to paragraphs 52-78. Genentech denies the remaining allegations in paragraph 145, and further denies that it engaged in any unlawful or improper conduct.

146. Genentech admits that it filed summary adjudication motions in the Civil Action and that Celltech opposed Genentech's motions for summary adjudication, and, subject to any applicable protective order, refers to Genentech's and Celltech's motion papers for their content. Genentech denies the remaining allegations in paragraph 146.

147. Genentech denies the allegations in paragraph 147.

148. Genentech refers to and incorporates its answers to paragraphs 52-78. Genentech denies the remaining allegations in paragraph 148.

149. Genentech refers to and incorporates its answers to paragraphs 79-91. Genentech denies the remaining allegations in paragraph 149.

150. Genentech refers to and incorporates its answers to paragraphs 79-91. Genentech denies the remaining allegations in paragraph 150, and further denies that it engaged in any unlawful or improper conduct.

151. Genentech refers to and incorporates its answers to paragraphs 92-99. Genentech denies the remaining allegations in paragraph 151, and further denies that it engaged in any unlawful or improper conduct.

152. Genentech refers to and incorporates its answers to paragraphs 92-99. Genentech denies the remaining allegations in paragraph 152, and further denies that it engaged in any unlawful or improper conduct.

153. Genentech refers to and incorporates its answers to paragraphs 100-106. Genentech denies the remaining allegations in paragraph 153, and further denies that it engaged in any unlawful or improper conduct.

154. Genentech refers to and incorporates its answers to paragraphs 100-106. Genentech denies the remaining allegations in paragraph 154, and further denies that it engaged in any unlawful or improper conduct.

155. Genentech denies the allegations in paragraph 155, and further denies that it engaged in any unlawful or improper conduct.

156. Genentech denies the allegations in paragraph 156, and further denies that it engaged in any unlawful or improper conduct.

157. Genentech denies the allegations in paragraph 157, and further denies that it engaged in any unlawful or improper conduct.

158. Genentech denies the allegations in paragraph 158, and further denies that it engaged in any unlawful or improper conduct.

159. Genentech denies the allegations in paragraph 159, and further denies that it engaged in any unlawful or improper conduct.

160. Genentech denies the allegations in paragraph 160.

161. Genentech admits that MedImmune purports to "seeks a declaratory judgment that the New Cabilly Patent is unenforceable," but denies that Genentech has committed any wrongful act or acts and denies that MedImmune is entitled to a declaratory judgment, or to any relief whatsoever.

FOURTH CAUSE OF ACTION

NON-INFRINGEMENT

(Against Genentech and COH)

162. Genentech repeats and realleges its answers to paragraphs 1 through 161 above.

163. Inasmuch as the averments of paragraph 163 purport to state legal conclusions, no response thereto is required. Genentech denies that MedImmune is entitled to the relief it seeks, or to any relief, and further denies the remaining allegations in paragraph 163.

164. Genentech admits that MedImmune purports to seek declaratory relief but denies that MedImmune is entitled to a declaratory judgment, or to any relief whatsoever.

FIFTH CAUSE OF ACTION

SECTION 1 OF THE SHERMAN ACT

(Against Genentech and Celltech)

165. Genentech repeats and realleges its answers to paragraphs 1 through 164 above.

166. Genentech denies the allegations in paragraph 166, and further denies that it engaged in any unlawful or improper conduct.

167. Genentech denies the allegations in paragraph 167, and further denies that it engaged in any unlawful or improper conduct.

168. Inasmuch as the averments of paragraph 168 purport to state legal conclusions, no response thereto is required. To the extent this paragraph avers facts, Genentech denies those averments.

169. Genentech denies the allegations in paragraph 169, and further denies that it engaged in any unlawful or improper conduct.

170. Genentech denies the allegations in paragraph 170, and further denies that it engaged in any unlawful or improper conduct.

171. Genentech denies the allegations in paragraph 171, and further denies that it engaged in any unlawful or improper conduct.

172. Genentech denies the allegations in paragraph 172, and further denies that it engaged in any unlawful or improper conduct.

173. Genentech denies the allegations of paragraph 173, and further denies that MedImmune is entitled to any relief or recovery whatsoever. Genentech notes that the Court has already dismissed, with prejudice, MedImmune's purported claim for unjust enrichment.

SIXTH CAUSE OF ACTION

SECTION 2 OF THE SHERMAN ACT

(CONSPIRACY TO MONOPOLIZE)

(Against Genentech and Celltech)

174. Genentech repeats and realleges its answers to paragraphs 1 through 173 above.

175. Genentech denies the allegations in paragraph 175, and further denies that it engaged in any unlawful or improper conduct.

176. Genentech denies the allegations in paragraph 176, and further denies that it engaged in any unlawful or improper conduct.

177. Inasmuch as the averments of paragraph 177 purport to state legal conclusions, no response thereto is required. To the extent this paragraph avers facts, Genentech denies those averments.

178. Genentech denies the allegations in paragraph 178.

179. Genentech denies the allegations in paragraph 179, and further denies that it engaged in any unlawful or improper conduct.

180. Genentech denies the allegations in paragraph 180, and further denies that MedImmune is entitled to any recovery or relief whatsoever. Genentech notes that the Court has already dismissed, with prejudice, MedImmune's purported claim for unjust enrichment

SEVENTH CAUSE OF ACTION

SECTION 2 OF THE SHERMAN ACT

(MONOPOLIZATION BY GENENTECH)

(Against Genentech)

181. Genentech repeats and realleges its answers to paragraphs 1 through 180 above.

182. Genentech denies the allegations in paragraph 182.

183. Genentech denies the allegations in paragraph 183, and further denies that it engaged in any unlawful or improper conduct.

184. Genentech denies the allegations in paragraph 184, and further denies that it engaged in any unlawful or improper conduct.

185. Genentech denies the allegations in paragraph 185, and further denies that MedImmune is entitled to any recovery or relief whatsoever. Genentech notes that the Court has already dismissed, with prejudice, MedImmune's purported claim for unjust enrichment.

EIGHTH CAUSE OF ACTION

TEE CARTWRIGHT ACT

(UNLAWFUL RESTRAINT OF TRADE)

(Against Genentech and Celltech)

186. Genentech repeats and realleges its answers to paragraphs 1 through 185 above.

187. Genentech denies the allegations in paragraph 187, and further denies that it engaged in any unlawful or improper conduct.

188. Genentech denies the allegations in paragraph 188, and further denies that it engaged in any unlawful or improper conduct.

189. Inasmuch as the averments of paragraph 189 purport to state legal conclusions, no response thereto is required. To the extent this paragraph avers facts, Genentech denies those averments.

190. Genentech denies the allegations in paragraph 190.

191. Genentech denies the allegations in paragraph 191, and further denies that MedImmune is entitled to any recovery or relief whatsoever. Genentech notes that the Court has already dismissed, with prejudice, MedImmune's purported claim for unjust enrichment

NINTH CAUSE OF ACTION

THE CARTWRIGHT ACT

(CONSPIRACY TO MONOPOLIZE)

(Against Genentech and Celltech)

192. Genentech repeats and realleges its answers to paragraphs 1 through 191 above.

193. Genentech denies the allegations in paragraph 193, and further denies that it engaged in any unlawful or improper conduct.

194. Genentech denies the allegations in paragraph 194, and further denies that it engaged in any unlawful or improper conduct.

195. Inasmuch as the averments of paragraph 195 purport to state legal conclusions, no response thereto is required. To the extent this paragraph avers facts, Genentech denies those averments.

196. Genentech denies the allegations in paragraph 196, and further denies that it engaged in any unlawful or improper conduct.

197. Genentech denies the allegations in paragraph 197, and further denies that it engaged in any unlawful or improper conduct.

198. Genentech denies the allegations in paragraph 198, and further denies that MedImmune is entitled to any recovery or relief whatsoever. Genentech notes that the Court has already dismissed, with prejudice, MedImmune's purported claim for unjust enrichment.

TENTH CAUSE OF ACTION

SECTION 17200 OF

THE CALIFORNIA BUSINESS AND PROFESSIONS CODE

(Against Genentech and Celltech)

199. Genentech repeats and realleges its answers to paragraphs 1 through 198 above.

200. Genentech denies the allegations in paragraph 200, and further denies that it engaged in any unlawful or improper conduct.

201. Genentech denies the allegations in paragraph 201, and further denies that MedImmune is entitled to any recovery or relief whatsoever. Genentech notes that the Court has already dismissed, with prejudice, MedImmune's purported claim for unjust enrichment.

WHEREFORE, defendant Genentech denies that plaintiff is entitled to any relief whatsoever and respectfully requests judgment dismissing the complaint with prejudice and with costs and attorneys' fees, as may be allowed by law, and such further relief as the Court deems appropriate.

Defendant Genentech denies each and every allegation of the complaint not specifically herein admitted.

AFFIRMATIVE DEFENSES

Genentech states the following affirmative defenses without assuming the burden of proof on such defenses that would otherwise rest on plaintiff.

First Affirmative Defense

The First Amended Complaint, and each claim for relief, fails to state a claim upon which relief may be granted.

Second Affirmative Defense

Plaintiff failed to mitigate any damages purportedly suffered as a result of the conduct alleged in the complaint.

Third Affirmative Defense

Plaintiff's claims are barred, in whole or in part because any conduct engaged in by Genentech has been reasonable and based on independent, legitimate business and economic justifications, without any purpose or intent to injure competition.

Fourth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the competition privilege.

Fifth Affirmative Defense

Each of the claims in the complaint, in whole or in part, is barred by the doctrines of waiver, laches, and estoppel.

Sixth Affirmative Defense

Each of the claims in the complaint, in whole or in part, is barred by the doctrine of unclean hands.

Seventh Affirmative Defense

Plaintiff's claims are barred to the extent that Plaintiff's purported injuries and damages were not proximately caused by acts or omissions of Genentech. There is no causal relationship between the losses alleged, if any, and any alleged wrongful acts or omissions by Genentech.

Eighth Affirmative Defense

Plaintiff's claims are barred, in whole or in part, by the applicable statutes of limitation.

Ninth Affirmative Defense

Any injury suffered by the plaintiff is not an injury which the antitrust laws are designed to prevent, or which flows from anything which would make Genentech's alleged conduct unlawful under the patent or antitrust laws.

Tenth Affirmative Defense

Plaintiff has waived each of the claims alleged in the complaint, in whole or in part.

Eleventh Affirmative Defense

Some or all of Genentech's conduct challenged by plaintiff is protected conduct under the *Noerr-Pennington* Doctrine, the First Amendment, and/or other related doctrines.

Twelfth Affirmative Defense

Plaintiff's claims are barred to the extent that plaintiff's claimed injuries and damages were not proximately caused by any acts or omissions of Genentech.

Thirteenth Affirmative Defense

Plaintiff has an adequate remedy at law and no basis exists for the grant of equitable relief.

Fourteenth Affirmative Defense

The Second, Third, and Fourth causes of action are barred by the U.S. patent laws.

Fifteenth Affirmative Defense

Plaintiff lacks standing to bring the causes of action asserted in the First Amended Complaint.

Sixteenth Affirmative Defense

Genentech hereby adopts and incorporates by this reference any and all other affirmative defenses asserted or to be asserted by any other defendant in this proceeding to the extent that defendants may share in such affirmative defenses.

Seventeenth Affirmative Defense

Genentech has not knowingly and intentionally waived any applicable affirmative defense and reserves the right to raise additional affirmative defenses as they become known to it through discovery in this matter. Genentech further reserves the right to amend its answer and/or affirmative defenses accordingly and/or to delete affirmative defenses that it determines are not applicable during the course of subsequent discovery.

PRAYER FOR RELIEF

WHEREFORE Genentech requests relief as follows:

1. That MedImmune's claims be dismissed with prejudice;

2. That MedImmune take nothing by reason of its First Amended Complaint;

3. That MedImmune's request for injunctive relief be denied;

4. For the cost of this suit, including reasonable attorney's fees and interest; and

5. For such other and further relief as the Court may deem proper.

Dated: September 2, 2003 Respectfully submitted,

LATHAM & WATKINS LLP
Daniel M. Wall
Mark A. Flagel
Dean G. Dunlavey
James K. Lynch

By: /s/ Mark A. Flagel
Mark A. Flagel
Genentech, Inc.

DEMAND FOR JURY TRIAL

Genentech hereby demands a trial by jury for all issues so triable in this action.

Dated: September 2, 2003 Respectfully submitted,

LATHAM & WATKINS LLP
Daniel M. Wall
Mark A. Flagel
Dean G. Dunlavey
James K. Lynch

By: /s/ Mark A. Flagel
MARK A. FLAGEL
Attorneys for Defendant
Genentech, Inc.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

Case No. CV-03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

DEFENDANT CITY OF HOPE NATIONAL MEDICAL CENTER'S ANSWER

DEMAND FOR JURY TRIAL

Defendant City of Hope, by counsel, hereby answers the First Amended Complaint filed by Plaintiff MedImmune, Inc. ("MedImmune"), and states as follows. The numbered paragraphs herein correspond to the numbered paragraphs of the First Amended Complaint.

1. City of Hope admits that the First Amended Complaint purports to state a claim for declaratory relief pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §§ 2201 and 2202. City of Hope admits that it is organized under the laws of the state of California and that its principal place of operation is in California. City of Hope further admits that Genentech, Inc. has its principal place of business in California and that Celltech filed a complaint in the United States District Court for the Northern District of California captioned *Celltech R&D Ltd. v. Genentech, Inc.*, Civ. Act. 01-3560 JCS. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 1 of the First Amended Complaint, and therefore denies them.

except that inasmuch as the allegations of jurisdiction purport to state legal conclusions, no response thereto is required.

2. Because the allegation of venue in paragraph 2 of the First Amended Complaint purports to state legal conclusions, no response thereto is required.

3. City of Hope admits that the First Amended Complaint purports to state claims under the legal theories cited in paragraph 3, but denies that MedImmune is entitled to any relief under those theories. City of Hope denies the other allegations of paragraph 3 of the First Amended Complaint.

4. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 4 of the First Amended Complaint, and therefore denies them.

5. City of Hope admits that MedImmune sells a product under the name Synagis. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 5 of the First Amended Complaint, and therefore denies them.

6. City of Hope admits the allegations of paragraph 6 of the First Amended Complaint.

7. City of Hope admits the allegations of paragraph 7 of the First Amended Complaint.

8. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 8 of the First Amended Complaint, and therefore denies them.

9. City of Hope admits that the First Amended Complaint includes a claim for declaratory relief, but denies that MedImmune is entitled to any such relief. City of Hope denies the other allegations of paragraph 9 of the First Amended Complaint.

10. City of Hope admits that Celltech and Genentech altered into an agreement or agreements (collectively, the "Agreement"). City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 10 of the First Amended Complaint, and therefore denies them.

11. City of Hope admits that Celltech and Genentech entered into the Agreement and the terms of that Agreement will speak for itself. City of Hope further admits that Celltech and Genentech were involved in an interference in the PTO that was resolved in favor Celltech. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 11 of the First Amended Complaint, and therefore denies them.

12. City of Hope admits that Celltech and Genentech entered into the Agreement prior to March 16, 2001. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 12 of the First Amended Complaint, and therefore denies them.

13. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 13 of the First Amended Complaint, and therefore denies them.

14. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 14 of the First Amended Complaint, and therefore denies them.

15. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 15 of the First Amended Complaint, and therefore denies them.

16. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 16 of the First Amended Complaint, and therefore denies them.

17. City of Hope admits that the U.S. Patent No. 6,331,415 BI (the "New Cabilly Patent") will expire in 2018. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 17 of the First Amended Complaint, and therefore denies them.

18. City of Hope admits that MedImmune makes payments to Genentech under a 1997 License Agreement, and that the 1997 License Agreement will speak for itself. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 18 of the First Amended Complaint, and therefore denies them.

19. City of Hope admits that the First Amended Complaint purports to state claims under the cited statutes and legal theories, but denies that MedImmune is entitled to any such relief. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 19 of the First Amended Complaint, and therefore denies them.

20. City of Hope admits that the First Amended Complaint seeks declaratory relief but denies that MedImmune is entitled to any such relief. City of Hope denies the remaining allegations of paragraph 20.

21. City of Hope admits the allegations of paragraph 21 of the First Amended Complaint.

22. City of Hope admits that the '567 patent was issued on March 28, 1989, based on Patent Application Serial No. 06/483,457.

23. City of Hope admits that a continuation of U.S. Patent Application Serial No. 06/483,457 was filed on June 10, 1988, and that it was assigned U.S. Patent Application Serial No. 07/205,419.

24. City of Hope admits the allegation of paragraph 24 of the First Amended Complaint.

25. City of Hope admits that the PTO Board of Patent Interferences and Appeals (the "PTO Board") initiated an interference proceeding to determine priority of invention between U.S. Patent Application No. 07/205,419 (the "New Cabilly Application") and U.S. Patent No. 4,816,397 (the "Boss Patent"). City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 25 of the First Amended Complaint, and therefore denies them.

26. City of Hope admits that on February 28, 1991, the PTO Board declared Patent Interference No. 102,572 between certain claims of the New Cabilly Application and the Boss Patent. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 26 of the First Amended Complaint, and therefore denies them.

27. City of Hope admits that Patent Interference No. 102,572 was declared on February 28, 1991, that the final decision of the PTO Board was issued on August 13, 1998 and that Genentech and Celltech made arguments to the PTO Board about priority. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 27 of the First Amended Complaint, and therefore denies them.

28. City of Hope admits that the PTO Board issued a final decision on August 13, 1998 and that final decision speaks for itself. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations

of paragraph 28 of the First Amended Complaint, and therefore denies them.

29. City of Hope admits that, on October 9, 1998, Genentech initiated a civil action under 35 U.S.C. § 146 entitled *Genentech, Inc. v. Celltech R&D Ltd.*, Case No. C98-3926 MMC (the "Civil Action"), in the United States District Court for the Northern District of California. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 29 of the First Amended Complaint, and therefore denies them.

30. City of Hope admits that the Civil Action was filed on October 9, 1998 and judgment was entered by the district court on March 16, 2001. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 30 of the First Amended Complaint, and therefore denies them.

31. City of Hope admits that Schmuel Cabilly had in his possession a draft patent application (the "Draft Cabilly Application") dated February 25, 1983, that Genentech asserted contentions about the Draft Cabilly Application including in its summary adjudication motion, and that Genentech's statements speak for themselves. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 31 of the First Amended Complaint, and therefore denies then.

32. City of Hope admits the Genentech moved for summary adjudication in the Civil Action and that Genentech's motion papers speak for themselves. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 32 of the First Amended Complaint, and therefore denies them.

33. City of Hope admits that Celltech opposed Genentech's motion for summary judgment in the Civil Action and that Celltech's opposition papers speak for themselves. City

of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 33 of the First Amended Complaint, and therefore denies them.

34. City of Hope admits that Genentech filed a reply brief in support of its motion for summary judgment and that Genentech's reply brief speaks for itself. City of Hope further admits that Genentech moved for summary adjudication that Celltech was not entitled to the March 25, 1983 priority date and that Genentech's motion papers speak for themselves. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 34 of the First Amended Complaint, and therefore denies them.

35. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 35 of the First Amended Complaint, and therefore denies them. Insofar as the allegations of paragraph 35 purport to state legal conclusions, no response thereto is required.

36. City of Hope admits that Genentech and Celltech entered into the Agreement. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 36 of the First Amended Complaint, and therefore denies them. Insofar as the allegations of paragraph 35 purport to state legal conclusions, no response thereto is required.

37. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 37 of the First Amended Complaint, and therefore denies them. Insofar as the allegations of paragraph 37 purport to state legal conclusions, no response thereto is required.

38. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 38 of the First Amended Complaint, and therefore denies them. Insofar as the allegations of paragraph 38 purport to state legal conclusions, no response thereto is required.

39. City of Hope admits that Genentech and Celltech submitted a proposed order to the District Court, and that proposed order speaks for itself. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 39 of the First Amended Complaint, and therefore denies them.

40. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 40 of the First Amended Complaint, and therefore denies them. Insofar as the allegations of paragraph 40 purport to state legal conclusions, no response thereto is required.

41. City of Hope admits that the District Court issued an order on March 16, 2001 and that the order and Genentech's and Celltech's proposed order speak for themselves. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 41 of the First Amended Complaint, and therefore denies them.

42. City of Hope admits that there is an order dated March 16, 2001 and that order speaks for itself. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 42 of the First Amended Complaint, and therefore denies them.

43. City of Hope admits that, following entry of the District Court's judgment, the PTO Board issued a Final Order After District Court Judgment, and that PTO Board order speaks for itself. City of Hope lacks sufficient knowledge to

form a belief or understanding as to the truth of the other allegations of paragraph 43 of the First Amended Complaint, and therefore denies them.

44. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 44 of the First Amended Complaint, and therefore denies them.

45. City of Hope admits that the PTO Board issued a Final Order After District Court Judgment and that the PTO Board order speaks for itself. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 45 of the First Amended Complaint, and therefore denies them.

46. City of Hope admits that the PTO Board issued a Final Order After District Court Judgment and that the PTO Board order speaks for itself. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 46 of the First Amended Complaint, and therefore denies them.

47. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 47 of the First Amended Complaint, and therefore denies them.

48. City of Hope admits that the PTO Board referred the New Cabilly Application to a patent examiner to continue prosecution. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 48 of the First Amended Complaint, and therefore denies them.

49. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 49 of the First Amended Complaint, and therefore denies them.

50. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 50 of the First Amended Complaint, and therefore denies them.

51. City of Hope denies the allegations of paragraph 51 of the First Amended Complaint

52. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 52 of the First Amended Complaint, and therefore denies them.

53. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 53 of the First Amended Complaint, and therefore denies them.

54. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 54 of the First Amended Complaint, and therefore denies them.

55. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 54 of the First Amended Complaint, and therefore denies them.

56. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 56 of the First Amended Complaint, and therefore denies them.

57. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 57 of the First Amended Complaint, and therefore denies them.

58. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 58 of the First Amended Complaint, and therefore denies them.

59. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 59 of the First Amended Complaint, and therefore denies them.

60. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 60 of the First Amended Complaint, and therefore denies them.

61. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 61 of the First Amended Complaint, and therefore denies them.

62. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope denies that the Draft Cabilly Application was not enabling. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 62 of the First Amended Complaint, and therefore denies them.

63. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope denies that the Cabilly Patent is not entitled to priority of invention. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 63 of the First Amended Complaint, and therefore denies than.

64. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope denies that Draft Cabilly Application was not enabling. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 64 of the First Amended Complaint, and therefore denies them.

65. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a

response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 65 of the First Amended Complaint, and therefore denies them.

66. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 66 of the First Amended Complaint, and therefore denies them.

67. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope denies that there were defects in the enablement of the invention. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 67 of the First Amended Complaint, and therefore denies them.

68. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 68 of the First Amended Complaint, and therefore denies them.

69. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 69 of the First Amended Complaint, and therefore denies them.

70. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 70 of the First Amended Complaint, and therefore denies them.

71. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 71 of the First Amended Complaint, and therefore denies them.

72. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 72 of the First Amended Complaint, and therefore denies them.

73. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 73 of the First Amended Complaint, and therefore denies them.

74. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 74 of the First Amended Complaint, and therefore denies them.

75. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 75 of the First Amended Complaint, and therefore denies them.

76. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 76 of the First Amended Complaint, and therefore denies them.

77. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 77 of the First Amended Complaint, and therefore denies them.

78. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 78 of the First Amended Complaint, and therefore denies them.

79. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 79 of the First Amended Complaint, and therefore denies them.

80. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope admits that Genentech filed an Information Disclosure Statement ("IDS") dated September 18, 1991 and that the IDS speaks for itself. City of Hope lacks sufficient knowledge as to the truth of the other allegations of paragraph 78 of the First Amended Complaint, and therefore denies than.

81. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 81 of the First Amended Complaint, and therefore denies them.

82. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 82 of the First Amended Complaint, and therefore denies them.

83. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 83 of the First Amended Complaint, and therefore denies them.

84. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a

belief or understanding as to the truth of the allegations of paragraph 84 of the First Amended Complaint, and therefore denies them.

85. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 85 of the First Amended Complaint, and therefore denies them.

86. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 86 of the First Amended Complaint, and therefore denies them.

87. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 87 of the First Amended Complaint, and therefore denies them.

88. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 88 of the First Amended Complaint, and therefore denies them.

89. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a

response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 89 of the First Amended Complaint, and therefore denies them.

90. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 90 of the First Amended Complaint, and therefore denies them.

91. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 91 of the First Amended Complaint, and therefore denies them.

92. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 92 of the First Amended Complaint, and therefore denies them.

93. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 93 of the First Amended Complaint, and therefore denies them.

94. These allegations do not relate to City of Hope and contain legal conclusions and therefore require no response.

To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 94 of the First Amended Complaint, and therefore denies them.

95. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 95 of the First Amended Complaint, and therefore denies them.

96. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope denies the allegations of paragraph 96 of the First Amended Complaint.

97. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 97 of the First Amended Complaint, and therefore denies them.

98. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 98 of the First Amended Complaint, and therefore denies them.

99. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a

response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 99 of the First Amended Complaint, and therefore denies them.

100. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 100 of the First Amended Complaint, and therefore denies them.

101. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 101 of the First Amended Complaint, and therefore denies them.

102. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 102 of the First Amended Complaint, and therefore denies them.

103. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the troth of the allegations of paragraph 103 of the First Amended Complaint, and therefore denies them.

104. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is

deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 104 of the First Amended Complaint, and therefore denies them.

105. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 105 of the First Amended Complaint, and therefore denies them.

106. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 106 of the First Amended Complaint, and therefore denies them.

107. City of Hope admits that the New Cabilly Patent issued on December 18, 2001. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 107 of the First Amended Complaint, and therefore denies them.

108. City of Hope admits that the New Cabilly Patent issued, and that it speaks for itself.

109. City of Hope admits that the New Cabilly Patent issued, and that it speaks for itself. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 109 of the First Amended Complaint, and therefore denies them.

110. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is

deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 110 of the First Amended Complaint, and therefore denies them.

111. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 111 of the First Amended Complaint, and therefore denies them.

112. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 112 of the First Amended Complaint, and therefore denies them, except that insofar as the allegations of paragraph 112 purport to state legal conclusions, no response thereto is required.

113. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 113 of the First Amended Complaint, and therefore denies them.

114. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 114 of the First Amended Complaint, and therefore denies them.

115. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 115 of the First Amended Complaint, and therefore denies them.

116. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 116 of the First Amended Complaint, and therefore denies them.

117. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 117 of the First Amended Complaint, and therefore denies them.

118. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 118 of the First Amended Complaint, and therefore denies them.

119. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope admits that MedImmune makes royalty payments to Genentech. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of

the other allegations of paragraph 119 of the First Amended Complaint, and therefore denies them.

120. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 120 of the First Amended Complaint, and therefore denies them.

121. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 121 of the First Amended Complaint, and therefore denies them.

122. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 122 of the First Amended Complaint, and therefore denies them.

123. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 123 of the First Amended Complaint, and therefore denies them.

124. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope admits that Genentech has the right to

issue licenses under the New Cabilly Patent that may result in royalty payments. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the other allegations of paragraph 124 of the First Amended Complaint, and therefore denies them.

125. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 125 of the First Amended Complaint, and therefore denies them.

126. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 126 of the First Amended Complaint, and therefore denies them.

127. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 127 of the First Amended Complaint, and therefore denies them.

128. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 128 of the First Amended Complaint, and therefore denies them.

129. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 129 of the First Amended Complaint, and therefore denies them. Insofar as the allegations of paragraph 129 purport to state legal conclusions, no response thereto is required.

130. These allegations do not relate to City of Hope and therefore require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 130 of the First Amended Complaint, and therefore denies them, except that insofar as the allegations of paragraph 130 purport to state legal conclusions, no response thereto is required.

FIRST CAUSE OF ACTION:

DECLARATORY JUDGMENT ON CONTRACTUAL RIGHTS AND OBLIGATIONS

(Against Genentech)

131. In response to the allegations of paragraph 131 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-130 as if fully set forth herein.

132. Inasmuch as the allegations of paragraph 132 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 132 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

133. Inasmuch as the allegations of paragraph 133 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 133 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

SECOND CAUSE OF ACTION:

PATENT INVALIDITY

(Against Genentech and City of Hope)

134. In response to the allegations of paragraph 134 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-133 as if fully set forth herein.

135. City of Hope denies the allegations of paragraph 135.

136. City of Hope denies the allegations of paragraph 136.

137. City of Hope denies the allegations of paragraph 137.

138. City of Hope denies the allegations of paragraph 138.

139. City of Hope admits that MedImmune seeks declaratory judgment, but denies that MedImmune is entitled to such relief.

THIRD CAUSE OF ACTION:

PATENT UNENFORCEABILITY

(Against Genentech and City of Hope)

140. In response to the allegations of paragraph 140 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-139 as if fully set forth herein.

141. City of Hope denies the allegations of paragraph 141 of the First Amended Complaint.

142. City of Hope denies the allegations of paragraph 142 of the First Amended Complaint.

143. City of Hope denies the allegation of paragraph 143 of the First Amended Complaint.

144. City of Hope denies the allegation of paragraph 144 of the First Amended Complaint.

145. City of Hope incorporates its answers to paragraphs 52 through 78. City of Hope denies the other allegation of paragraph 145 of the First Amended Complaint.

146. To the extent these allegations do not relate to City of Hope, they require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope denies that the Draft Cabilly Application lacked enabling disclosure of the claimed invention. City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth the other allegations of paragraph 146 of the First Amended Complaint, and therefore denies them.

147. City of Hope denies the allegations of paragraph 147 of the First Amended Complaint.

148. City of Hope denies the allegations of paragraph 148 of the First Amended Complaint.

149. City of Hope incorporates its answers to paragraphs 79 through 91. City of Hope denies the other allegations of paragraph 149 of the First Amended Complaint.

150. City of Hope incorporates its answers to paragraphs 79 through 91. City of Hope denies the other allegations of paragraph 150 of the First Amended Complaint.

151. City of Hope incorporates its answers to paragraphs 92 through 99. City of Hope denies the other allegations of Paragraph 151 of the First Amended Complaint.

152. City of Hope incorporates its answers to paragraphs 92 through 99. City of Hope denies the other allegations of paragraph 152 of the First Amended Complaint.

153. City of Hope incorporates its answers to paragraphs 100 through 106. City of Hope denies the other allegations of paragraph 153 of the First Amended Complaint.

154. City of Hope incorporates its answers to paragraphs 100 through 106. City of Hope denies the other allegations of paragraph 154 of the First Amended Complaint.

155. City of Hope denies the allegation of paragraph 155 of the First Amended Complaint.

156. To the extent these allegations do not relate to City of Hope, they require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 156 of the First Amended Complaint, and therefore denies them.

157. To the extent these allegations do not relate to City of Hope, they require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 157 of the First Amended Complaint, and therefore denies them.

158. To the extent these allegations do not relate to City of Hope, they require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require a response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 158 of the First Amended Complaint, and therefore denies them.

159. To the extent these allegations do not relate to City of Hope, they require no response. To the extent this paragraph is deemed to relate to City of Hope or otherwise to require response, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations of paragraph 159 of the First Amended Complaint, and therefore denies them.

160. City of Hope denies the allegations of paragraph 160 of the First Amended Complaint.

161. City of Hope admits that MedImmune seeks declaratory judgment, but denies that MedImmune is entitled to such relief.

FOURTH CAUSE OF ACTION:

NON-INFRINGEMENT

(Against Genentech and City of Hope)

162. In response to the allegations of paragraph 162 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-161 as if fully set forth herein.

163. City of Hops denies the allegations of paragraph 163 of the First Amended Complaint.

164. City of Hope admits that MedImmune seeks declaratory judgment, but denies that MedImmune is entitled to such relief.

FIFTH CAUSE OF ACTION:

SECTION 1 OF THE SHERMAN ACT

(Against Genentech and Celltech)

165. In response to the allegations of paragraph 165 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-164 as if fully set forth herein.

166. Inasmuch as the allegations of paragraph 166 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 166 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

167. Inasmuch is the allegations of paragraph 167 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 167 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

168. Inasmuch as the allegations of paragraph 168 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 168 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

169. Inasmuch as the allegations of paragraph 169 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 169 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

170. Inasmuch as the allegations of paragraph 170 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 170 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

171. Inasmuch as the allegations of paragraph 171 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 171 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

172. Inasmuch the allegations of paragraph 172 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 172 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

173. Inasmuch as the allegations of paragraph 173 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 173 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

SIXTH CAUSE OF ACTION:

SECTION 2 OF THE SHERMAN ACT
CONSPIRACY TO MONOPOLY

(Against Genentech and Celltech)

174. In response to the allegations of paragraph 174 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-173 as if fully set forth herein.

175. Inasmuch as the allegations of paragraph 175 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 175 alleges facts and is

deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

176. Inasmuch as the allegations of paragraph 176 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 176 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

177. Inasmuch as the allegations of paragraph 177 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 177 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

178. Inasmuch as the allegations of paragraph 178 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 178 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

179. Inasmuch as the allegations of paragraph 179 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 179 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

180. Inasmuch as the allegations of paragraph 180 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is

required. To the extent that paragraph 180 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

SEVENTH CAUSE OF ACTION:

SECTION 2 OF THE SHERMAN ACT (MONOPOLIZATION BY GENENTECH

(Against Genentech)

181. In response to the allegations of paragraph 181 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-180 as if fully set forth herein.

182. Inasmuch as the allegations of paragraph 182 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 182 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

183. Inasmuch as the allegations of paragraph 183 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 183 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

184. Inasmuch as the allegations of paragraph 184 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 184 alleges facts and is deemed to relate to city of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

185. Inasmuch as the allegations of paragraph 185 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 185 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

EIGHTH CAUSE OF ACTION:

THE CARTWRIGHT ACT
(UNLAWFUL RESTRAINT OF TRADE)

(Against Genentech and Celltech)

186. In response to the allegations of paragraph 186 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-185 as if fully set forth herein.

187. Inasmuch as the allegations of paragraph 187 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 187 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

188. Inasmuch as the allegations of paragraph 188 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 188 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

189. Inasmuch as the allegations of paragraph 189 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 189 alleges facts and is

deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

190. Inasmuch as the allegations of paragraph 190 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 190 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

191. Inasmuch as the allegations of paragraph 191 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 191 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

NINTH CAUSE OF ACTION:

THE CARTWRIGHT ACT
(CONSPIRACY TO MONOPOLIZE)

(Against Genentech and Celltech)

192. In response to the allegations of paragraph 192 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-191 as if fully set forth herein.

193. Inasmuch as the allegations of paragraph 193 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 193 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

194. Inasmuch as the allegations of paragraph 194 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 194 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

195. Inasmuch as the allegations of paragraph 195 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 195 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

196. Inasmuch as the allegations of paragraph 196 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 196 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

197. Inasmuch as the allegations of paragraph 197 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 197 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

198. Inasmuch as the allegations of paragraph 198 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 198 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

TENTH CAUSE OF ACTION:

SECTION 17200 OF THE CALIFORNIA BUSINESS & PROFESSIONS CODE

(Against Genentech and Celltech)

199. In response to the allegations of paragraph 199 of the First Amended Complaint, City of Hope incorporates its responses in paragraphs 1-198 as if fully set forth herein.

200. Inasmuch as the allegations of paragraph 200 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 200 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

201. Inasmuch as the allegations of paragraph 201 of the First Amended Complaint do not relate to City of Hope and purport to state legal conclusions, no response thereto is required. To the extent that paragraph 201 alleges facts and is deemed to relate to City of Hope, City of Hope lacks sufficient knowledge to form a belief or understanding as to the truth of the allegations, and therefore denies them.

PRAYER FOR RELIEF

1. Defendant denies each and every allegation and request for relief contained in paragraph 1 of the Prayer for Relief of the First Amended Complaint.

2. Defendant denies each and every allegation and request for relief contained in paragraph 2 of the Prayer for Relief of the First Amended Complaint.

3. Defendant denies each and every allegation and request for relief contained in paragraph 3 of the Prayer for Relief of the First Amended Complaint.

4. Defendant denies each and every allegation and request for relief contained in paragraph 4 of the Prayer for Relief of the First Amended Complaint.

5. Defendant denies each and every allegation and request for relief contained in paragraph 5 of the Prayer for Relief of the First Amended Complaint.

6. Defendant denies each and every allegation and request for relief contained in paragraph 6 of the Prayer for Relief of the First Amended Complaint.

7. Defendant denies each and every allegation and request for relief contained in paragraph 7 of the Prayer for Relief of the First Amended Complaint.

8. Defendant denies each and every allegation and request for relief contained in paragraph 8 of the Prayer for Relief of the First Amended Complaint.

9. Defendant denies each and every allegation and request for relief contained in paragraph 9 of the Prayer for Relief of the First Amended Complaint.

10. Defendant denies each and every allegation and request for relief contained in paragraph 10 of the Prayer for Relief of the First Amended Complaint.

AFFIRMATIVE DEFENSES

As separate and distinct affirmative defenses to the causes of action set forth in the Amended Complaint, but without assuming any additional burden of proof except as may otherwise exist based on MedImmune's claims and allegations, City of Hope alleges as follows:

FIRST AFFIRMATIVE DEFENSE

1. The First Amended Complaint, and each and every claim set forth therein, fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

2. MedImmune has an adequate remedy at law and no basis exists for the grant of equitable relief.

THIRD AFFIRMATIVE DEFENSE

3. MedImmune's claims are barred, in whole or in part, by the Noerr-Pennington doctrine, the First Amendment, and/or related doctrines.

FOURTH AFFIRMATIVE DEFENSE

4. MedImmune's claims are barred, in whole or in part, for failure to mitigate damages.

FIFTH AFFIRMATIVE DEFENSE

5. MedImmune's claims are barred, in whole or in part, by the equitable doctrine of unclean hands.

SIXTH AFFIRMATIVE DEFENSE

6. MedImmune's claims are barred, in whole or in part, by the doctrines of laches, waiver and/or estoppel.

SEVENTH AFFIRMATIVE DEFENSE

7. MedImmune has waived the claims asserted in its First Amended Complaint.

EIGHTH AFFIRMATIVE DEFENSE

8. MedImmune lacks standing to bring the claims asserted in its First Amended Complaint.

NINTH AFFIRMATIVE DEFENSE

9. MedImmune's claims are barred, in whole or in part, by the U.S. Patent laws.

TENTH AFFIRMATIVE DEFENSE

10. MedImmune's claims are barred, in whole or in part, because MedImmune's claimed injury was not caused by the acts or omissions of the defendants.

ELEVENTH AFFIRMATIVE DEFENSE

11. MedImmune's claims are barred, in whole or in part, by the applicable statutes of limitation.

TWELFTH AFFIRMATIVE DEFENSE

12. MedImmune's claims are barred, in whole or in part, by the competition privilege.

THIRTEENTH AFFIRMATIVE DEFENSE

13. City of Hope incorporates by reference all affirmative defenses of any other defendant in this proceeding to the extent these affirmative defenses relate to City of Hope.

FOURTEENTH AFFIRMATIVE DEFENSE

14. City of Hope reserves its right to raise additional affirmative defenses as they become known to City of Hope. City of Hope reserves the right to amend its answer accordingly and/or to delete affirmative defenses it determines are not applicable.

Prayer for Relief

WHEREFORE, City of Hope requests relief as follows:

1. That MedImmune's claims be dismissed;

2. That MedImmune take nothing by reason of its First Amended Complaint;

3. That MedImmune's request for injunctive relief by [*sic*] denied;

4. For the cost of this suit, including reasonable attorney's fees; and

5. For such other and further relief as the Court may deem proper.

Dated: September 2, 2003

IRELL & MANELLA LLP
Morgan Chn (70446)
David I. Gindler (117824)
Joseph M. Lipner (155735)

By: /s/ Joseph M. Lipner
JOSEPH M. LIPNER
Attorneys for Defendant
CITY OF HOPE

JURY DEMAND

Defendant city of Hope hereby demands a trial by jury on all claims and issues so triable.

Dated: September 2, 2003

IRELL & MANELLA LLP
Morgan Chu (70446)
David I. Gindler (117824)
Joseph M. Lipner (155735)

By: /s/ Joseph M. Lipner
JOSEPH M. LIPNER
Attorneys for Defendant
CITY OF HOPE

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

Case No. CV 03-02567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

CELLTECH R&D LTD.'S AMENDED ANSWER TO FIRST AMENDED COMPLAINT

DEMAND FOR JURY TRIAL

Defendant Celltech R&D Ltd. ("Celltech") hereby answers the First Amended Complaint of MedImmune, Inc. ("MedImmune") and alleges as follows:

Jurisdiction and Venue

1. Celltech admits that the Complaint purports to state a claim for declaratory relief pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. §§ 2201 and 2202. Celltech further admits that it filed a complaint in the United States District Court for the Northern District of California captioned *Celltech R&D Ltd. v. Genentech, Inc.*, Civ. Act. 01-3560 JCS. Celltech admits, on information and belief, that Genentech, Inc. ("Genentech") has its principal place of business in South San Francisco, California. Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments concerning the principal place of business and place of organization of City of Hope. Celltech denies all other aver-

ments of Paragraph 1, except that inasmuch as the averments of jurisdiction purport to state legal conclusions, no response thereto is required.

2. Celltech denies the averments of Paragraph 2, except that inasmuch as the averments of venue purport to state legal conclusions, no response thereto is required.

The Parties

3. Celltech admits that the Complaint purports to state claims under the cited legal theories, but denies that Plaintiff is entitled to any relief under those causes of action. Celltech denies all other averments of Paragraph 3, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

4. Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 4, and on that basis denies those averments.

5. Celltech admits that Plaintiff sells a product under the name Synagis. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 5, and on that basis denies those averments.

6. Celltech admits on information and belief that Genentech is a Delaware corporation with its principal place of business in South San Francisco, California.

7. Celltech admits that U.S. Patent No. 6,331,415 B1 states that City of Hope of Duarte, California is an assignee of the patent. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 7, and on that basis denies those averments.

8. Celltech admits that it is a British company with its principal place of business at 208 Bath Road, Slough, Berkshire, SL 1 WE, United Kingdom. Celltech admits that

the Medical Research Council granted a sub-license to MedImmune under U.S. Patent No. 4,816,397 (the "Boss Patent").

9. Celltech admits that the Complaint includes a demand for declaratory relief, but denies that Plaintiff is entitled to any such relief. Celltech denies each and every other averment set forth in Paragraph 9.

10. Celltech admits that it entered into certain agreements with Genentech to settle a patent interference relating to the Boss Patent and U.S. Patent Application No. 205,419 (the "Cabilly Application"), and to secure for Celltech a license to certain rights under U.S. Patent No. 6,331,415 B1 (the "Cabilly Patent"). Celltech further admits that the details of those agreements are confidential and proprietary. Celltech denies each and every other averment set forth in Paragraph 10.

11. Celltech admits that it entered into certain agreements with Genentech to settle a patent interference relating to the Boss Patent and the Cabilly Application, and to secure for Celltech a license to certain rights under the Cabilly Patent. Celltech further admits that it prevailed in the patent interference (Interference No. 102,572) before the PTO Board of Patent Interferences and Appeals and that Judge Maxine M. Chesney of the United States District Court for the Northern District of California denied Genentech's motion for summary judgment in the § 146 interference proceeding that was initiated by Genentech. Celltech denies each and every other averment set forth in Paragraph 11.

12. Celltech admits that, prior to March 16, 2001, it entered into certain agreements with Genentech to settle legal proceedings relating to Boss Patent and the Cabilly Application, and to secure for Celltech a license to certain rights under the Cabilly Patent. Celltech denies each and every other averment set forth in Paragraph 12.

13. Celltech admits that its 2001 Annual Report states that "Celltech has secured preferential access for its development programmes to the Cabilly patent, which covers the production of a broad range of antibody or antibody fragment products, for its 17 year life." Celltech further admits that a Celltech press release dated December 18, 2001 states: "By this settlement, Celltech will be compensated by Genentech in terms of income from sales of products which would otherwise have been covered by the Boss patent until its normal expiry date in 2006." Celltech denies each and every other averment set forth in Paragraph 13.

14. Inasmuch as the averments of Paragraph 14 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 14, and on that basis denies those averments.

15. Celltech admits that Celltech and the Medical Research Council granted several licenses to the Boss patent. Celltech further admits that the original term of the Boss patent would have expired on March 28, 2006. Celltech denies each and every other averment set forth in Paragraph 15.

16. Inasmuch as the averments of Paragraph 16 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 16, and on that basis denies those averments.

17. Celltech admits that the term of the Cabilly Patent will expire in 2018. Celltech denies each and every other averment set forth in Paragraph 17.

18. Inasmuch as the averments of Paragraph 18 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech

is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 18, and on that basis denies those averments.

19. Celltech admits that the Complaint purports to state claims under the cited statutes and legal theories, but denies that Plaintiff is entitled to any such relief. Celltech denies each and every other averment set forth in Paragraph 19.

20. Celltech admits that the Complaint demands declaratory relief, but denies that Plaintiff is entitled to any such relief. Celltech denies each and every other averment set forth in Paragraph 20.

21. Celltech admits that U.S. Patent No. 4,816,567 states that Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel filed U.S. Patent Application No. 483,457 on April 8, 1983. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 21, and on that basis denies those averments.

22. Celltech admits that U.S. Patent No. 4,816,567 states that it issued on March 28, 1989, based on U.S. Patent Application No. 483,457. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 22, and on that basis denies those averments.

23. Celltech admits that U.S. Patent No. 6,331,415 B1 states that U.S. Patent Application 07/205,419 was filed on June 10, 1988, as a continuation of U.S. Patent Application 06/483,457. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 23, and on that basis denies those averments.

24. Celltech admits that U.S. Patent No. 4,816,567 and U.S. Patent No. 4,816,397 were both issued by the PTO on March 28, 1989.

25. Celltech admits that Genentech amended its Cabilly Application and sought to provoke an interference with the Boss patent. Celltech further admits that Patent Interference No. 102,572 was declared by the PTO on February 28, 1991. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 25, and on that basis denies those averments, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

26. Celltech admits that, on February 28, 1991, the PTO Board of Patent Interferences and Appeals declared Patent Interference No. 102,572 between certain claims of the Cabilly Application and the Boss Patent. Celltech denies each and every other averment set forth in Paragraph 26, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

27. Celltech admits that Patent Interference No. 102,572 was declared on February 28, 1991 and that the final decision of the PTO Board of Patent Appeals and Interferences was issued on August 13, 1998. Celltech admits that both Celltech and Genentech made arguments to the PTO Board of Patent Appeals and Interferences relating to priority of invention. Celltech denies each and every other averment set forth in Paragraph 27.

28. Celltech admits that final decision of the PTO Board of Patent Appeals and Interferences, issued on August 13, 1998, entered judgment in favor of the Celltech inventors, and refers to that decision for its content. Celltech denies each and every other averment set forth in Paragraph 28.

29. Celltech admits that, on October 9, 1998, Genentech initiated a civil action under 35 U.S.C. § 146 entitled *Genentech, Inc. v. Celltech R&D Ltd.*, Case No. C98-3926 MMC (the "Civil Action"), in the United States District Court for the Northern District of California. Celltech denies each and every other averment set forth in Paragraph 29.

30. Celltech admits that the Civil Action was filed on October 9, 1998 and judgment was entered by the district court on March 16, 2001. Celltech admits that the Civil Action included depositions, document production, and expert disclosures. Celltech denies each and every other averment set forth in Paragraph 30.

31. Celltech admits that, during the course of the Civil Action, Genentech produced a draft Cabilly patent application. Celltech admits that Genentech made certain contentions regarding the draft Cabilly patent application, including statements made in Genentech's summary judgment papers filed in the Civil Action, and refers to Genentech's motion papers for their content. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 31, and on that basis denies those averments.

32. Celltech admits that Genentech moved in the Civil Action for summary judgment in its favor, and refers to Genentech's motion papers for their content. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 32, and on that basis denies those averments, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

33. Celltech admits that it opposed Genentech's motion for summary judgment in the Civil Action, and refers to its motion papers for their content. Celltech denies each and every other averment set forth in Paragraph 33, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

34. Celltech admits that Genentech filed a reply brief in support of its motion for summary judgment, and refers to Genentech's motion papers for their content. Celltech admits that Genentech filed a motion for summary judgment that

Celltech was not entitled to priority to the March 25, 1983 filing date of the United Kingdom Boss patent application, and refers to Genentech's motion papers for their content. Celltech denies each and every other averment set forth in Paragraph 34.

35. Celltech admits that summary judgment motions were filed in the Civil Action, and refers to the papers filed by the parties for their content. Celltech denies each and every other averment set forth in Paragraph 35, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

36. Celltech admits that it entered into certain agreements with Genentech to settle a patent interference relating to the Boss Patent and the Cabilly Application, and to secure for Celltech a license to certain rights under the Cabilly Patent. Celltech further admits that it prevailed in the patent interference before the PTO Board of Patent Interferences and Appeals and that Judge Maxine M. Chesney of the United States District Court for the Northern District of California denied Genentech's motion for summary judgment in the § 146 interference proceeding that was initiated by Genentech. Celltech denies each and every other averment set forth in Paragraph 36.

37. Celltech denies each and every averment set forth in Paragraph 37, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

38. Celltech denies each and every averment set forth in Paragraph 38, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

39. Celltech admits that in connection with their settlement agreement, Genentech and Celltech submitted a proposed order to the District Court, and that the proposed order contained several proposed findings of fact and conclusions of law, including a proposed finding that "Genentech is

entitled as a matter of law to priority over Celltech to invention described by the count." Celltech denies each and every other averment set forth in Paragraph 39, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

40. Celltech denies each and every averment set forth in Paragraph 40, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

41. Celltech admits that the District Court executed the proposed order and entered that Order on March 16, 2001, and refers to the Order for its content. Celltech denies each and every other averment set forth in Paragraph 41.

42. Celltech admits the District Court entered a Judgment in the Civil Action, and refers to the Judgment for is content. Celltech further admits that, among other things, the District Court's Judgment directed the PTO to: "vacate the PTO's decision in *Cabilly et al. v. Boss et al.*, Patent Interference No. 102,572"; "revoke and vacate United States Patent No. 4,816,397, issued March 28, 1989 to Boss *et al.*"; and "grant and issue to Genentech's Inventors (with Genentech as the assignee), with the issue date being the same as the date of revocation of United States Patent No. 4,816,397, a United States patent . . . ." Celltech denies each and every other averment set forth in paragraph 42.

43. Celltech admits that, following entry of the District Court's Judgment, the PTO Board of Patent Interferences and Appeals issued a Final Order After District Court Judgment, and refers to the Final Order for its terms. Celltech denies each and every other averment set forth in Paragraph 43.

44. Celltech denies each and every averment set forth in Paragraph 44.

45. Celltech admits that the PTO Board of Patent Interferences and Appeals' Final Order After District Court Judg-

ment stated, in part, "[w]e will note that if a patent is issued to Cabilly, its term will begin to run now and the public has already been subject to patent rights of Boss since 1989, and that the interference has been pending since 1991." Celltech refers to the Final Order for its terms. Celltech denies each and every other averment set forth in Paragraph 45.

46. Celltech admits that the PTO Board of Patent Interferences and Appeals issued a Final Order After District Court Judgment, and refers to the Final Order for its terms. Celltech denies each and every other averment set forth in Paragraph 46.

47. Celltech admits that it commenced a civil action, *Celltech R&D Ltd. v. Genentech, Inc.*, in the United States District Court for the Northern District of California pursuant to 35 U.S.C. § 146. Celltech denies each and every other averment set forth in Paragraph 47.

48. Inasmuch as the averments of Paragraph 48 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits the PTO Board of Patent Interferences and Appeals referred the Cabilly Application to a patent examiner. Celltech denies each and every other averment set forth in Paragraph 48.

49. Inasmuch as the averments of Paragraph 49 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 49, and on that basis denies those averments.

50. Inasmuch as the averments of Paragraph 50 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 50, and on that basis denies those averments.

51. Inasmuch as the averments of Paragraph 51 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 51, and on that basis denies those averments.

52. Inasmuch as the averments of Paragraph 52 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 52, and on that basis denies those averments.

53. Inasmuch as the averments of Paragraph 53 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that it presented expert evidence during the Civil Action and that it opposed Genentech's motions for summary judgment. Celltech refers to the papers filed by Celltech for their content. Celltech denies each and every other averment set forth in Paragraph 53.

54. Inasmuch as the averments of Paragraph 54 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that it submitted an expert report by Dr. Jonathan S. Weissman and refers to the report for its content. Celltech denies each and every other averment set forth in Paragraph 54.

55. Inasmuch as the averments of Paragraph 55 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech referenced a draft Cabilly patent application in its summary judgment briefing regarding priority. Celltech further admits that a draft Cabilly patent application is referenced in the March-16, 2001 Order Re-

garding Resolution of Interference. Celltech refers to the draft Cabilly patent application for its content Celltech is without knowledge or information sufficient to form a belief as to the truth of the remaining averments in Paragraph 55, and on that basis denies those averments.

56. Inasmuch as the averments of Paragraph 56 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 56, and on that basis denies those averments.

57. Inasmuch as the averments of Paragraph 57 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech responded to the arguments raised in Celltech's opposition to Genentech's motion for summary judgment. Celltech refers to the papers filed by Genentech for their content. Celltech denies the remaining allegations of Paragraph 57.

58. Inasmuch as the averments of Paragraph 58 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech moved for summary judgment regarding the Celltech British Application. Celltech refers to the papers filed by Genentech for their content. Celltech denies the remaining allegations of Paragraph 58.

59. Inasmuch as the averments of Paragraph 59 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that during the Civil Action, counsel for Genentech took the deposition of Celltech's expert Dr. Weissman. Celltech refers to the deposition transcript for its content. Celltech denies the remaining allegations of Paragraph 59.

60. Inasmuch as the averments of Paragraph 60 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech moved for summary judgment regarding the Celltech British Application. Celltech refers to the papers filed by Genentech for their content. Celltech denies the remaining allegations of Paragraph 60.

61. Inasmuch as the averments of Paragraph 61 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech moved for summary judgment during the Civil Action. Celltech refers to the papers filed by Genentech for their content. Celltech denies the remaining allegations of Paragraph 61.

62. Inasmuch as the averments of Paragraph 62 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech moved for summary judgment during the Civil Action. Celltech refers to the papers filed by Genentech for their content. Celltech denies the remaining allegations of Paragraph 62.

63. Inasmuch as the averments of Paragraph 63 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 63, and on that basis denies those averments.

64. Inasmuch as the averments of Paragraph 64 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech denies each and every averment set forth in Paragraph 64.

65. Inasmuch as the averments of Paragraph 65 do not relate to Celltech, no response thereto is required. To the

extent this Paragraph is deemed to relate to Celltech, Celltech denies each and every averment set forth in Paragraph 65.

66. Inasmuch as the averments of Paragraph 66 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that it entered into certain agreements with Genentech to settle the Civil Action. Celltech denies each and every other averment set forth in Paragraph 66.

67. Inasmuch as the averments of Paragraph 67 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 67, and on that basis denies those averments.

68. Inasmuch as the averments of Paragraph 68 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 68, and on that basis denies those averments.

69. Inasmuch as the averments of Paragraph 69 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 69, and on that basis denies those averments.

70. Inasmuch as the averments of Paragraph 70 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 70, and on that basis denies those averments.

71. Inasmuch as the averments of Paragraph 71 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 71, and on that basis denies those averments.

72. Inasmuch as the averments of Paragraph 72 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 72, and on that basis denies those averments.

73. Inasmuch as the averments of Paragaph 73 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 73, and on that basis denies those averments.

74. Inasmuch as the averments of Paragraph 74 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 74, and on that basis denies those averments.

75. Inasmuch as the averments of Paragraph 75 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 75, and on that basis denies those averments.

76. Inasmuch as the averments of Paragraph 76 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 76, and on that basis denies those averments.

77. Inasmuch as the averments of Paragraph 77 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 77, and on that basis denies those averments.

78. Inasmuch as the averments of Paragraph 78 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 78, and on that basis denies those averments.

79. Inasmuch as the averments of Paragraph 79 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 79, and on that basis denies those averments.

80. Inasmuch as the averments of Paragraph 80 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech submitted an Information Disclosure Statement on September 18, 1991 and refers to that document for its content. Celltech denies the remaining allegations of Paragraph 80.

81. Inasmuch as the averments of Paragraph 81 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech submitted an Information Disclosure Statement on September 18, 1991 and refers to that document for its content. Celltech denies the remaining allegations of Paragraph 81.

82. Inasmuch as the averments of Paragraph 82 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech filed a Notice of Opposition with the European Patent Office regarding the European Boss Patent. Celltech refers to those documents for their contents. Celltech denies the remaining allegations of Paragraph 82.

83. Inasmuch as the averments of Paragraph 83 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech filed a Notice of Opposition with the European Patent Office regarding the European Boss Patent. Celltech refers to that document for its contents. Celltech denies the remaining allegations of Paragraph 83.

84. Inasmuch as the averments of Paragraph 84 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that Genentech filed a Notice of Opposition with the European Patent Office regarding the European Boss Patent. Celltech refers to that document for its contents. Celltech denies the remaining allegations of Paragraph 84.

85. Inasmuch as the averments of Paragraph 85 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 85, and on that basis denies those averments.

86. Inasmuch as the averments of Paragraph 86 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 86, and on that basis denies those averments.

87. Inasmuch as the averments of Paragraph 87 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Board issued an order dated July 25, 2001 and refers to the order for its content. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 87, and on that basis denies those averments.

88. Inasmuch as the averments of Paragraph 88 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 88, and on that basis denies those averments.

89. Inasmuch as the averments of Paragraph 89 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 89, and on that basis denies those averments.

90. Inasmuch as the averments of Paragraph 90 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge

or information sufficient to form a belief as to the truth of the averments in Paragraph 90, and on that basis denies those averments.

91. Inasmuch as the averments of Paragraph 91 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 91, and on that basis denies those averments.

92. Inasmuch as the averments of Paragraph 92 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 92, and on that basis denies those averments.

93. Inasmuch as the averments of Paragraph 93 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 93, and on that basis denies those averments.

94. Inasmuch as the averments of Paragraph 94 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 94, and on that basis denies those averments.

95. Inasmuch as the averments of Paragraph 95 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 95, and on that basis denies those averments.

96. Inasmuch as the averments of Paragraph 96 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 96, and on that basis denies those averments.

97. Inasmuch as the averments of Paragraph 97 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech refers to the Stanford Application for its content, and Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 97, and on that basis denies those averments.

98. Inasmuch as the averments of Paragraph 98 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 98, and on that basis denies those averments.

99. Inasmuch as the averments of Paragraph 99 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 99, and on that basis denies those averments.

100. Inasmuch as the averments of Paragraph 100 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 100, and on that basis denies those averments.

101. Inasmuch as the averments of Paragraph 101 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech refers to the Axel patents for their contents, and Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 101, and on that basis denies those averments.

102. Inasmuch as the averments of Paragraph 102 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 102, and on that basis denies those averments.

103. Inasmuch as the averments of Paragraph 103 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 103, and on that basis denies those averments.

104. Inasmuch as the averments of Paragraph 104 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 104, and on that basis denies those averments.

105. Inasmuch as the averments of Paragraph 105 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech refers to the Axel patents for their contents, and Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 105, and on that basis denies those averments.

106. Inasmuch as the averments of Paragraph 106 purport to state legal conclusions and do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 106, and on that basis denies those averments.

107. Inasmuch as the averments of Paragraph 107 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that U.S. Patent No. 6,331,415 B1, issued on December 18, 2001. Celltech is without knowledge or information sufficient to form a belief as to the truth of every other averment in Paragraph 107, and on that basis denies those averments.

108. Inasmuch as the averments of Paragraph 108 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that U.S. Patent No. 6,331,415 B1 is titled "Method of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein," and lists Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel as inventors. Celltech further admits that the patent lists Genentech as the assignee and that a Certificate of Correction issued by the PTO on June 25, 2002 added City of Hope as an additional assignee. Celltech is without knowledge or information sufficient to form a belief as to the truth of every other averment in Paragraph 108, and on that basis denies those averments.

109. Inasmuch as the averments of Paragraph 109 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech. Celltech admits that certain antibody molecules can be used to provide beneficial treatment for certain illnesses. Celltech is without knowledge or information sufficient to form a belief as to the

truth of every other averment in Paragraph 109, and on that basis denies those averments.

110. Celltech admits that it issued a press release on December 18, 2001, denies that MedImmune has accurately quoted the press release, and refers to the press release for its terms. Celltech further admits that the press release stated, in part, that "By this settlement, Celltech will be compensated by Genentech in terms of income from sales of products which would otherwise have been covered by the Boss Patent until its normal expiry date in 2006." Celltech denies each and every other averment set forth in Paragraph 110.

111. Celltech admits that it issued a press release on December 18, 2001, denies that MedImmune has accurately quoted the press release, and refers to the press release for its terms. Celltech further admits that the press release stated, in part, that "Celltech has also secured rights to Genentech's Cabilly patent for its products." Celltech denies each and every other averment set forth in Paragraph 111.

112. Celltech admits the referenced Senate Report contains the quoted language. Celltech further admits that Celltech and Genentech filed their settlement agreement with the PTO under seal pursuant to applicable PTO rules and procedures. Celltech denies each and every other averment of Paragraph 112, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

113. Inasmuch as the averments of Paragraph 113 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 113, and on that basis denies those averments.

114. Inasmuch as the averments of Paragraph 114 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech

is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 114, and on that basis denies those averments.

115. Celltech admits that, on May 8, 2002, Plaintiff petitioned the PTO for access to Celltech's and Genentech's settlement agreement, and that Celltech and Genentech opposed that petition pursuant to applicable rules of the PTO. Celltech further states that, on April 4, 2003, the PTO Board of Patent Interferences and Appeals rejected Plaintiff's petition, finding that the petition "appears to constitute a 'fishing expedition' that cannot be granted absent, as respondents have indicated, 'something more' constituting the requisite 'good cause.'" Celltech denies each and every other averment set forth in Paragraph 115.

116. Inasmuch as the averments of Paragraph 116 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 116, and on that basis denies those averments.

117. Inasmuch as the averments of Paragraph 117 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 117, and on that basis denies those averments.

118. Inasmuch as the averments of Paragraph 118 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 118, and on that basis denies those averments.

119. Inasmuch as the averments of Paragraph 119 do not relate to Celltech, no response thereto is required. To the

extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 119, and on that basis denies those averments.

120. Celltech denies each and every averment set forth in Paragraph 120.

121. Celltech admits that it owned the Boss patent. Celltech further admits that it granted to the Medical Research Council in London a license to the Boss patent, which license included the right to grant sublicenses, and refers to the sublicenses granted by Medical Research Council for their terms. Celltech denies each and every other averment set forth in Paragraph 121.

122. Celltech admits that Plaintiff, as well as several other individuals and entities, obtained a sublicense to the Boss patent. Celltech denies each and every other averment set forth in Paragraph 122.

123. Celltech denies each and every averment set forth in Paragraph 123.

124. Inasmuch as the averments of Paragraph 124 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 124, and on that basis denies those averments.

125. Inasmuch as the averments of Paragraph 125 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 125, and on that basis denies those averments.

126. Inasmuch as the averments of Paragraph 126 purport to state legal conclusions, no response thereto is required. To

the extent a response is required, Celltech denies each and every averment set forth in Paragraph 126.

127. Inasmuch as the averments of Paragraph 127 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 127, and on that basis denies those averments.

128. Inasmuch as the averments of Paragraph 128 purport to state legal conclusions, no response thereto is required. To the extent a response is required, Celltech denies each and every averment set forth in Paragraph 128.

129. Celltech denies that it engaged in unlawful conduct. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 129, and on that basis denies those averments.

130. Celltech denies that it engaged in unlawful conduct. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 130, and on that basis denies those averments.

First Cause of Action
Declaratory Judgment on Contractual Rights and Obligations
(Against Genentech)

131. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 130 of this Answer as if fully set forth herein.

132. Inasmuch as the averments of Paragraph 132 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 132, and on that basis denies those averments.

133. Inasmuch as the averments of paragraph 133 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Complaint purports to state a claim for declaratory judgment. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 133, and on that basis denies those averments.

Second Cause of Action
Patent Invalidity
(Against Genentech and City of Hope)

134. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 133 of this Answer as if fully set forth herein.

135. Inasmuch as the averments of Paragraph 135 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 135, and on that basis denies those averments.

136. Inasmuch as the averments of Paragraph 136 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 136, and on that basis denies those averments.

137. Inasmuch as the averments of Paragraph 137 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief

as to the truth of the averments in Paragraph 137, and on that basis denies those averments.

138. Inasmuch as the averments of Paragraph 138 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 138, and on that basis denies those averments.

139. Inasmuch as the averments of Paragraph 139 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Complaint purports to state a claim for declaratory judgment. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 139, and on that basis denies those averments.

Third Cause of Action
Patent Unenforceability
(Against Genentech and City of Hope)

140. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 139 of this Answer as if fully set forth herein.

141. Inasmuch as the averments of Paragraph 141 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 141, and on that basis denies those averments.

142. Inasmuch as the averments of Paragraph 142 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph

avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 142, and on that basis denies those averments.

143. Inasmuch as the averments of Paragraph 143 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 143, and on that basis denies those averments.

144. Celltech incorporates and restates its answers to the averments contained in Paragraphs 48 through 106 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 144 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 144, and on that basis denies those averments.

145. Celltech incorporates and restates its answers to the averments contained in Paragraphs 52 through 78 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 145 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 145, and on that basis denies those averments.

146. Celltech incorporates and restates its answers to the averments contained in Paragraphs 52 through 78 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 146 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the

extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 146, and on that basis denies those averments.

147. Inasmuch as the averments of Paragraph 147 do not relate to Celltech, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 147, and on that basis denies those averments.

148. Celltech incorporates and restates its answers to the averments contained in Paragraphs 66 and 76-77 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 148 do not relate to Celltech, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 148, and on that basis denies those averments.

149. Celltech incorporates and restates its answers to the averments contained in Paragraphs 79-91 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 149 do not relate to Celltech, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 149, and on that basis denies those averments.

150. Celltech incorporates and restates its answers to the averments contained in Paragraphs 79-91 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 150 do not relate to Celltech, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or informa-

tion sufficient to form a belief as to the truth of the averments in Paragraph 150, and on that basis denies those averments.

151. Celltech incorporates and restates its answers to the averments contained in Paragraphs 92-99 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 151 do not relate to Celltech, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 151, and on that basis denies those averments.

152. Celltech incorporates and restates its answers to the averments contained in Paragraphs 92-99 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 152 do not relate to Celltech, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 152, and on that basis denies those averments.

153. Celltech incorporates and restates its answers to the averments contained in Paragraphs 100-106 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 153 do not relate to Celltech, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 153, and on that basis denies those averments.

154. Celltech incorporates and restates its answers to the averments contained in Paragraphs 100-106 of this Answer as if fully set forth herein. Inasmuch as the averments of Paragraph 154 do not relate to Celltech, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the

averments in Paragraph 154, and on that basis denies those averments.

155. Inasmuch as the averments of Paragraph 155 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments a Paragraph 155, and on that basis denies those averments.

156. Inasmuch as the averments of Paragraph 156 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 156, and on that basis denies those averments.

157. Inasmuch as the averments of Paragraph 157 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 157, and on that basis denies those averments.

158. Inasmuch as the averments of Paragraph 158 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 158, and on that basis denies those averments.

159. Inasmuch as the averments of Paragraph 159 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 159, and on that basis denies those averments.

160. Inasmuch as the averments of Paragraph 160 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 160, and on that basis denies those averments.

161. Inasmuch as the averments of Paragraph 161 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Complaint purports to state a claim for declaratory judgment. Celltech is without knowledge or information sufficient to form a belief as to the truth of the other averments in Paragraph 161, and on that basis denies those averments.

Fourth Cause of Action
Non-Infringement
(Against Genentech and City of Hope)

162. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 161 of this Answer as if fully set forth herein.

163. Inasmuch as the averments of Paragraph 163 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 163, and on that basis denies those averments.

164. Inasmuch as the averments of Paragraph 164 do not relate to Celltech, no response thereto is required. To the extent this Paragraph is deemed to relate to Celltech, Celltech admits that the Complaint purports to state a claim for declaratory judgment. Celltech is without knowledge or information sufficient to form a belief as to the truth of the

other averments in Paragraph 164, and on that basis denies those averments.

Fifth Cause of Action
Section 1 of the Sherman Act
(Against Genentech and Celltech)

165. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 164 of this Answer as if fully set forth herein.

166. Celltech denies each and every averment set forth in Paragraph 166.

167. Celltech denies each and every averment set forth in Paragraph 167.

168. Celltech denies each and every averment set forth in Paragraph 168, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

169. Celltech denies each and every averment set forth in Paragraph 169.

170. Celltech denies each and every averment set forth in Paragraph 170, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

171. Celltech denies each and every averment set forth in Paragraph 171, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

172. Celltech denies each and every averment set forth in Paragraph 172, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

173. Celltech denies that Plaintiff is entitled to any relief under Section 1 of the Sherman Act and denies each and every other averment set forth in Paragraph 173, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Sixth Cause of Action
Section 2 of the Sherman Act (Conspiracy to Monopolize)
(Against Genentech and Celltech)

174. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 173 of this Answer as if fully set forth herein.

175. Celltech denies each and every averment set forth in Paragraph 175.

176. Celltech denies each and every averment set forth in Paragraph 176.

177. Celltech denies each and every averment set forth in Paragraph 177, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

178. Celltech denies each and every averment set forth in Paragraph 178.

179. Celltech denies each and every averment set forth n Paragraph 179 except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

180. Celltech denies that Plaintiff is entitled to any relief under Section 2 of the Sherman Act and denies each and every averment set forth in Paragraph 180, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Seventh Cause of Action
Section 2 of the Sherman Act
(Against Genentech)

181. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 180 of this Answer as if fully set forth herein.

182. Inasmuch as the averments of Paragraph 182 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph

avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 182, and on that basis denies those averments.

183. Inasmuch as the averments of Paragraph 183 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 183, and on that basis denies those averments.

184. Inasmuch as the averments of Paragraph 184 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 184, and on that basis denies those averments.

185. Inasmuch as the averments of Paragraph 185 do not relate to Celltech and purport to state legal conclusions, no response thereto is required. To the extent this Paragraph avers facts and is deemed to relate to Celltech, Celltech is without knowledge or information sufficient to form a belief as to the truth of the averments in Paragraph 185, and on that basis denies those averments.

Eighth Cause of Action
The Cartwright Act (Unlawful Restraint of Trade)
(Against Genentech and Celltech)

186. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 185 of this Answer as if fully set forth herein.

187. Celltech denies each and every averment set forth in Paragraph 187.

188. Celltech denies each and every averment set forth in Paragraph 188.

189. Celltech denies each and every averment set forth in Paragraph 189, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

190. Celltech denies each and every averment set forth in Paragraph 190, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

191. Celltech denies that Plaintiff is entitled to any relief under the Cartwright Act and denies each and every other averment set forth in Paragraph 191, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required

Ninth Cause of Action
The Cartwright Act (Conspiracy to Monopolize)
(Against Genentech and Celltech)

192. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 191 of this Answer as if fully set forth herein.

193. Celltech denies each and every averment set forth in Paragraph 193.

194. Celltech denies each and every averment set forth in Paragraph 194.

195. Celltech denies each and every averment set forth in Paragraph 195, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

196. Celltech denies each and every averment set forth in Paragraph 196.

197. Celltech denies each and every averment set forth in Paragraph 197, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

198. Celltech denies that Plaintiff is entitled to any relief under the Cartwright Act and denies each and every averment set forth in Paragraph 198, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Tenth Cause of Action
Section 17200 of the California Business & Professions Code
(Against Genentech and Celltech)

199. Celltech incorporates and restates its answers to the averments contained in Paragraphs 1 through 198 of this Answer as if fully set forth herein.

200. Celltech denies each and every averment set forth in Paragraph 200, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

201. Celltech denies that Plaintiff is entitled any relief under Section 17200 and denies each and every averment set forth in Paragraph 201, except that inasmuch as the averments purport to state legal conclusions, no response thereto is required.

Affirmative Defenses

As for its further and separate defenses, Celltech states the following affirmative defenses without assuming the burden of proof on such defenses that would otherwise rest on Plaintiff.

First Affirmative Defense

202. The causes of action asserted in the Complaint fail to state a claim upon which relief may be granted.

Second Affirmative Defense

203. Plaintiff has an adequate remedy at law and no basis exists for the grant of equitable relief.

Third Affirmative Defense

204. Plaintiff's causes of action are barred by the *Noerr-Pennington* doctrine, the First Amendment and/or related doctrines.

Fourth Affirmative Defense

205. Plaintiff's claims are barred for failure to mitigate damages.

Fifth Affirmative Defense

206. Plaintiff's claims are barred to the extent that Plaintiff's purported injuries and damages were not proximately caused by any acts or omissions of Celltech.

Sixth Affirmative Defense

207. The Fifth, Sixth, Eighth, Ninth, and Tenth causes of action should be dismissed because Plaintiff has not suffered, and will not suffer, injury of the type the antitrust laws were designed to prevent.

Seventh Affirmative Defense

208. The equitable doctrine of unclean hands prevents the relief requested by Plaintiff.

Eighth Affirmative Defense

209. Any and all of Celltech's conduct challenged by Plaintiff was justified, constituted bona fide business competition, and was carried out in furtherance of Celltech's legitimate business objectives.

Ninth Affirmative Defense

210. The Fifth, Sixth, Eighth, Ninth, and Tenth causes of action are barred by the U.S. patent laws.

Tenth Affirmative Defense

211. Plaintiff's causes of action are barred by the equitable doctrines of waiver, laches, and estoppel.

Eleventh Affirmative Defense

212. Plaintiff lacks standing to the bring causes of action asserted in the Complaint.

Twelfth Affirmative Defense

213. Celltech hereby adopts and incorporates by reference all other affirmative defenses asserted by any other defendant in this proceeding to the extent these affirmative defenses relate to Celltech.

Prayer for Relief

WHEREFORE, Celltech requests relief as follows:

1. That Plaintiffs claims be dismissed;

2. That Plaintiff take nothing by reason of its Complaint for Damages;

3. That Plaintiff's request for injunctive relief be denied;

4. For the cost of this suit, including reasonable attorneys' fees; and

5. For such other and further relief as the Court may deem proper.

Demand for Jury Trial

Celltech hereby demands a trial by jury for all issues so triable in this action.

Dated: September 22, 2003

CHARLES S. BARQUIST
LORI A. SCHECHTER
STEVEN M. HAINES
JASON A. CROTTY
CHRISTOPHER P. WILLARD
MORRISON & FOERSTER LLP

By: _____
Charles S. Barquist
Attorney for Defendant
CELLTECH R&D LTD.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

Case No. CV 03-02567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE, AND CELLTECH R&D LTD.,

Defendants.

CELLTECH R&D LTD'S MOTION FOR JUDGMENT ON THE PLEADINGS

I. INTRODUCTION

MedImmune claims injuries under federal and state antitrust laws arising from the issuance of a U.S. patent to Genentech—and MedImmune's decision to license the patent rather than face infringement litigation—because the U.S. Patent and Trademark Office ("PTO") issued that patent only after Celltech and Genentech settled their litigation over which of them was the first inventor of the technology. In settling their priority litigation, Celltech and Genentech jointly sought an order from the U.S. District Court in San Francisco, and Genentech thereafter sought issuance of the patent from the PTO. However, the actions of Celltech and Genentech are immune under the *Noerr-Pennington* doctrine, which constitutionally immunizes petitioning the government, including courts and administrative agencies. The *Noerr-Pennington* doctrine bars MedImmune's claims under both federal and state law. The "sham" exception to *Noerr-Pennington* was not even alleged by MedImmune and is inapplicable in any event. The pleadings plainly demonstrate

that the actions complained of are those of a U.S. District Judge and the PTO, not Celltech or Genentech. Taking the allegations of the Complaint as true, Celltech is entitled to judgment on the pleadings on MedImmune's antitrust and unfair competition claims.

* * * *

V. CONCLUSION

For the reasons set forth above, MedImmune's federal antitrust claims (Counts 5 and 6), state law antitrust claims (Counts 8 and 9) and state law unfair competition claim (Count 10) fail as a matter of law and Celltech is entitled to judgment on the pleadings on those counts. The actions complained of are immune from liability because they are constitutionally protected petitioning immunized by the *Noerr-Pennington* doctrine.

Dated: September 29, 2003

CHARLES S. BARQUIST
LORI A. SCHECHTER
STEVEN M. HAINES
JASON A. CROTTY
CHRISTOPHER P. WILLARD
MORRISON & FOERSTER LLP

By: /s/ Steven M. Haines
STEVEN M. HAINES

Attorneys for Defendant
CELLTECH R&D LTD.

News
Release

[Logo]
CELLTECH

For immediate release

18th December 2001

CELLTECH AND GENENTECH SETTLE BOSS/CABILLY US PATENT INTERFERENCE

Celltech and Genentech have reached a settlement in the matter of the US Patent Office interference involving Celltech's 'Boss' patent application and Genentech's 'Cabilly' patent application, both of which relate to antibody manufacturing technology.

The settlement was concluded as a result of a mediation process ordered by the US District Court of the Northern District of California. Arising from this process, the settlement comes into effect following the recent grant of the Cabilly patent by the US Patent Office and an Order of the Court to revoke and withdraw the Boss patent and grant and issue the Cabilly patent.

By this settlement, Celltech will be compensated by Genentech in terms of income from sales of products which would otherwise have been covered by the Boss patent until its normal expiry date in 2006. Celltech has also secured rights to Genentech's Cabilly patent for its products.

Contacts:

Peter Allen	Chief Financial Officer	(44) (0) 1753 534655
Richard Bungay	Director of Corporate Communications & Strategic Planning	
Jon Coles	Brunswick (London)	(44) (0) 207 404 5959
Cindy Leggett-Flynn	Brunswick (New York)	(1) (212) 333 3810

Website: www.celltechgroup.com

Celltech Group plc (NYSE: CELL; LSE: CCH) is one of Europe's largest biopharmaceutical companies, with an extensive late stage development pipeline and a profitable cash-generative pharmaceutical business. Cellech also possesses drug discovery capabilities of exceptional strength, including a leading position in antibody engineering.

Celltech desires to take advantage of the "Safe Harbor" provisions of the US Private Securities Litigation Reform Act of 1995, with respect to forward looking statements contained within this document. In particular certain statements with regard to the future income receivable and rights granted under the terms of the agreement with Genentech are forward looking in nature. By their nature forward looking statements involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward looking statements. Other factors that could affect these forward-looking statements are described in the Company's reports filed with the U.S. Securities and Exchange Commission. The forward looking statements included in this document represent the Company's best judgment as of the date hereof based in part on preliminary information and certain assumptions which management believes to be reasonable. The Company disclaims any obligation to update these forward looking statements.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Case No. CV03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

GENENTECH, INC.'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT ON PLAINTIFF'S ANTITRUST CLAIMS; MEMORANDUM IN SUPPORT

NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE THAT at 10:00 a.m. on December 15, 2003, or as soon thereafter as the matter can be heard, before the Honorable Mariana R. Pfaelzer, in courtroom 12 of the United States District Court for the Central District if California, defendant Genentech, Inc. ("Genentech") will and hereby does move this Court pursuant to Rule 56 of the Federal Rules of Civil Procedurefor an order granting summary judgment on plaintiff MedImmune, Inc.'s Fifth, Sixth, Seventh, Eighth, Ninth, and Tenth causes of action. Genentech's motion is made on the grounds that MedImmune, Inc.'s alleged injury was caused by governmental action, namely the issuance of U.S. Patent No. 6,311,415B1, and therefore, Genentech is immune from antitrust liability under the *Noerr-Pennington* doctrine and also because MedImmune, Inc. has not suffered antitrust injury.

This motion is based on this Notice of Motion and Motion, on the Memorandum filed concurrently herewith, on the accompanying declarations of Vernon M. Winters, Sharon E. Crane, and Christopher S. Yates, all pleadings and papers on file in this action, and on the oral argument at the hearing on the motion.

This motion is made following the conference of counsel pursuant to Local Rule 7-3 which took place on October 10, 2003. This motion is made in accordance with the Stipulation and Order Regarding Briefing and Hearing Schedule filed October 23, 2003, a copy of which is attached hereto as Exhibit 1.

Date: October 30, 2003 Respectfully submitted,

LATHAM & WATKINS LLP
Daniel M. Wall
Mark A. Flagel
Dean G. Dunlavey
Christopher S. Yates
James K. Lynch

By Daniel M. Wall
DANIEL M. WALL
Attorneys for Defendant
Genentech, Inc.

[Exhibit omitted in printing.]

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Case No. CV 03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D Ltd.,

Defendants.

DECLARATION OF VERNON M. WINTERS

I, Vernon M. Winters, declare:

1. I am an attorney admitted to practice law in California and am a partner with the law firm Weil, Gotshal & Manges LLP. I have personal and firsthand knowledge of the facts stated in this declaration. If called upon to do so, I could and would testify competently thereto.

2. I was previously a partner with the law firm Latham & Watkins LLP and represented Genentech in *Genentech, Inc. v. Celltech Therapeutics, Ltd.*, Docket No. C98-3926 MMC (N.D. Cal) (the "146 Action").

3. I know from my representation of Genentech in the 146 Action that Genentech commenced the 146 Action on October 9, 1998. Attached hereto as Exhibit 1 is a true and correct copy of Genentech's Complaint in the 146 Action.

4. During the course of the 146 Action, I received and produced to Celltech a copy of a draft patent application dated February 25, 1983. Attached hereto as Exhibit 2 is a true and correct copy of that draft patent application as it was produced in the 146 Action. Attached hereto as Exhibit 3 is a true and correct copy of excerpts from the deposition of Dr.

Shmuel Cabilly taken in the 146 Action, including testimony concerning the February 25, 1983 draft patent application.

5. Attached hereto as Exhibit 4 is a true and correct copy of excerpts of the deposition of Dr. Kate Murashige taken in the 146 Action, including testimony concerning the February 25, 1983 draft patent application and a further draft patent application dated March 25, 1983. Attached hereto as Exhibit 5 is a true and correct copy of a declaration provided by Dr. Murashige during the 146 Action.

6. Attached hereto as Exhibit 6 is a true and correct copy of excerpts of the deposition of Dr. Herbert Heyneker taken in the 146 Action.

7. Attached hereto as Exhibit 7 is a true and correct copy of excerpts of the deposition of Dr. Arthur Riggs taken in the 146 Action.

8. Attached hereto as Exhibit 8 is a true and correct copy of excerpts of the deposition of Dr. Ronald Wetzel taken in the 146 Action.

9. Attached hereto as Exhibits 9-11 are true and correct copies of Genentech's memorandum in support of its motion for summary adjudication regarding conception in the 146 Action. Celltech's brief in opposition to that motion, and Genentech's reply brief in support of its motion. Celltech did not move for summary judgment or summary adjudication in the 146 Action.

10. On behalf of Genentech, I attended the July 28, 2000 hearing before the Honorable Maxine M. Chesney, United States District Judge, concerning Genentech's motions for summary adjudication. Attached hereto as Exhibit 12 is a true and correct copy of the transcript of that hearing.

11. After the July 28, 2000 hearing, Genentech and Celltech agreed to mediate the dispute before the Honorable William Cahill, a retired California Superior Court Judge who

was affiliated at the time with the mediation and arbitration service, JAMS.

12. On September 15, 2000, I participated in a mediation session with Judge Cahill. Thereafter, I participated in numerous discussions with counsel for Celltech concerning settlement and concerning settlement documents. In early 2001, the parties reached agreement on a settlement. Attached hereto as Exhibit 13 is a true and correct copy of "Settlement Agreement between Genentech, Inc. and Celltech Chiroscience Limited," dated March 2, 2001. Attached hereto as Exhibit 14 is a true and correct copy of "Amended and Restated License Agreement between Genentech, Inc. and Celltech Chiroscience Limited."

13. After Genentech and Celltech had executed the Settlement Agreement and the Amended and Restated License Agreement, I worked with counsel for Celltech to inform the Court of the settlement and to prepare documents for filing with the Court. Attached hereto as Exhibit 15 is a true and correct copy of a document entitled "Notice of Settlement and Joint Request for Entry of Settlement Instruments," filed on March 6, 2001. Attached hereto as Exhibit 16 is a true and correct copy of a proposed "Order Regarding Resolution of Interference," filed March 6, 2001. Attached hereto as Exhibit 17 is a true and correct copy of a proposed "Judgment" filed March 6, 2001. Attached hereto as Exhibits 18-19 are true and correct copies of a "Proposed Order Regarding Resolution of Interference" and a "Proposed Judgment" which were filed by the Court on March 16, 2001.

14. Attached hereto as Exhibit 20 is a true and correct copy of Genentech's memorandum in support of its motion for summary adjudication regarding diligence in the 146 Action.

15. Attached hereto as Exhibit 21 is a true and correct copy of "Civil Minutes" filed March 8, 2001 from the 146 Action.

Executed this 29th day of October, 2003, at San Francisco, California.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

/s/ Vernon M. Winters
VERNON M. WINTERS

[*Exhibit 1 to Winters Declaration*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

[Filed Oct. 9, 1998]

Case No. C 98-3926 CRB

GENENTECH, INC., a Delaware Corporation,
Plaintiff,

vs.

CELLTECH LIMITED, a British Company,
Defendant.

COMPLAINT FOR OVERTURNING A PATENT OFFICE DECISION IN AN INTERFERENCE

Plaintiff, Genentech Inc. ("Genentech"), for its complaint against Defendant Celltech Limited ("Celltech"), alleges:

JURISDICTION

1. This is an action for patent interference arising under the patent laws of the United States of America, particularly 35 U.S.C. § 146. This Court has jurisdiction of this action under 28 U.S.C. § 1338.

VENUE

2. Venue lies in this District under 28 U.S.C. § 1391(b), (c) and (d).

PARTIES

3. Plaintiff Genentech is a corporation duly organized and existing under the laws of Delaware and having its offices and principal place of business at One DNA Way, South San Francisco, California 94080.

4. Defendant Celltech is a British company having its offices and principal place of business at 216 Bath Road, Slough SL1 4EN, Berkshire, United Kingdom.

CLAIM FOR RELIEF

5. On April 8, 1983, Genentech, in the name of the inventors Shmuel Cabilly, Herbert L Heyneker, William E. Holmes, Arthur D. Riggs and Ronald B. Wetzel, filed an application for patent in the United States Patent and Trademark Office ("PTO"), which was given U.S. Serial No. 06/483,457. That application later issued as U.S. Patent 4,816,567, on March 28, 1989. Before issuance of that patent, a divisional application was filed on June 10, 1988, and was given Serial No. 07/205,419. These two applications are referred to as the "Cabilly" applications. The entire right, title, and interest in and to both of the Cabilly applications referred to in this paragraph were assigned, when filed, to Genentech.

6. Genentech, as the assignee of the entire right, title, and interest in and to the Cabilly applications identified in paragraph 5 above, has been and still is the owner of those applications. For those applications, Genentech was the owner of the entire right, title, and interest therein from the time they were filed, to the filing of this Complaint.

7. On November 14, 1984, Celltech, in the name of Michael A. Boss, John H. Kenten, John S. Emtage, and Clive R. Wood, as alleged co-inventors, filed an application in the PTO, and that application was given Serial No. 06/672.265. That application later issued as U.S. Patent 4,816,397 (the "Boss Patent"). on March 28. 1989. During proceedings in the PTO, Celltech was accorded the benefit of PCT application PCT/GB84/00094, filed March 23, 1984, and UK application No. 83/08235, filed March 25, 1983. These applications are referred to as the "Boss" applications. All three Boss applications were assigned to Celltech at the time

they were originally filed in 1983 and 1984, and since then the entire right, title and interest in the Boss applications and the Boss Patent has been owned by Celltech. Celltech was "the party in interest as shown by the records of the Patent and Trademark Office at the time of the decision complained of" herein (see 35 U.S.C. § 146).

8. As of August 13, 1998, the date of the decision complained of herein, the real parties in interest were Genentech and Celltech.

9. On or about March 9, 1990, Genentech, through an attorney, copied Claims 1-20 from the Boss Patent, for the purpose of provoking an interference. Claim 1 of the Boss Patent became the count of the interference. Pursuant to 35 U.S.C. § 135, an interference (No. 102,572) was declared on February 28, 1991, between the Cabilly application Serial No. 07/205,419, and the Boss Patent. The PTO found that an interference existed between claims 1-20 of the Boss Patent, on the one hand, and claims 101-120 of Cabilly application Serial No. 07/205,419, on the other hand.

10. Genentech's inventors, Shmuel Cabilly, Herbert L Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel, were the first inventors of the subject matter of the interference, and the inventors of the Boss Patent are not entitled to priority over the inventors in the Cabilly applications

11. The Boss inventors were not entitled to the award of priority for the reasons enumerated below, as well as such other and further reasons as will appear is the case proceeds.

12. Despite Boss never contesting that the Cabilly applications disclosed the invention of the count, and the earliest Cabilly application being filed less than two weeks after the earliest Boss application, the Board of Patent Appeals and Interferences of the United States Patent and Trademark Office (the "Board") rendered a final decision on August 13.

1998 (copy attached and marked as Exhibit A) awarding priority of the count in issue to the senior party, Boss. Genentech is dissatisfied with the decision of the Board and therefore has filed this action under 35 U.S.C. § 146. This decision of the Board was erroneous in both law and fact:

a. The Board wrongfully found that Cabilly did not prove, by a preponderance of evidence, an actual reduction to practice of the invention in issue prior to March 25, 1983, the filing date of the earliest Boss application;

b. The Board wrongfully found that the Cabilly record failed to show possession of the essential elements of the count in interference, namely production of molecules recited in the process of the count, and that the product of the process was useful; and

c. The Board also wrongfully found that Cabilly failed to show a complete conception of the count prior to the March 25, 1983, date accorded Boss.

WHEREFORE, Genentech prays:

1. That this Court reverse the decision of the Board dated August 13, 1998.

2. That this Court declare that Shmuel Cabilly, Herbert L Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel are the original and first inventors of the subject matter of claims 101-120 of the Cabilly application and claims 1-20 of the Boss Patent, that Cabilly is entitled to a patent containing the Cabilly claims mentioned in this prayer, and that the claims of the Boss Patent are unpatentable to Boss.

3. That this Court authorize the Commissioner of Patents and Trademarks to grant Cabilly a patent on their application Serial No. 07/205,419, containing claims 101-120.

4. That this Court award costs of suit and such further relief as may be necessary and proper.

Dated: October 9, 1998 Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.
R. Danny Huntington
Mary Ann Dillahunty
LATHAM & WATKINS
Paul H. Dawes
Alexander S. Pesic

By: /s/ Paul H. Dawes
Paul H. Dawes
Attorneys for Plaintiff
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[*Exhibit 2 to Winters Declaration*]

Genentech Inc.

February 25, 1983

Dr. Arthur Riggs
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Dear Dr. Riggs,

Enclosed for your review is the present draft of the patent application on the Recombinant Antibodies. Herb thought it appropriate to forward it to you at this point, although there is more material to be added to the Examples section.

Any suggestions or comments you or Schmuel may have would be welcome. I know there are data just arrived from Schmuel which are not included in this draft.

Sincerely

/s/ Kate H. Murashige
KATE H. MURASHIGE
Patent Attorney

Recombinant Hybrid Antibodies and Active Antibody Fragments *

Background of the Invention

This invention relates to the field of antibody production and to modification of naturally occuring antibody amino acid sequences. Specifically, the invention relates to useing recombinant techniques to produce both antibodies which are analogous to those normally found in mammalian systems and to take advantage of gene modification techniques to construct hybrid or other modified forms of antibodies.

A. *Mammalian Antibodies*

Antibodies are polypeptides produced by the mammalian immune system in response to challenge by foreign proteins, glycoproteins, cells, or other antigenic foreign substances. The sequence of events which permits the organism to overcome invasion by foreign cells or to rid the system of foreign substances is at least partially understood. An important part of this process is the manufacture of antibodies which bind specifically to a particular foreign substance. The binding specificity of such polypeptides to a particular antigen is highly refined, and the multitude of specificities capable of being generated by the individual mammal is remarkable in its complexity and variability. Thousands of antigens are capable of eliciting responses, each almost exclusively directed to the particular antigen which elicited it.

A.1. *Source and Utility*

Two major sources of mammalian antibodies are presently known—generation in site by the mammalian B lymphocytes and in cell culture by hybridomas. Antibodies are made in situ as a result of the differentiation of B lymphocytes which occurs in response to stimulation by specific antigens. In the

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* Handwritten marks illegible and omitted.

undifferentiated B cell, the portions of DNA coding for the various sequences on the antibody chains are separated in the genomic DNA. In response to antigen stimulation, certain of the sequences are reassembled sequentially prior to transcription. A review of this process has been given by Gough _____(1981). The resulting genome is capable of expression in the mature B lymphocyte to produce the desired antibodies. Even when only a single antigen is introduced into the sphere of the immune system for a particular mammal, the antibodies generated in response differ somewhat in their range of capability for cross reacting with other, similar, antigens, since slightly differing arrangements of the genome of the mature B cell are responsible for each production sequence, i.e., the antibodies are "polyclonal".

This limited but inherent heterogeneity has been overcome in numerous particular cases by use of hybridoma technology to create "monoclonal" antibodies. In this process, the serum from a mammal which has been injected with antigen is fractionated to recover antibody-producing mature B cells, and this mixture of B cells fused with a tumor cell line, thus producing a hybrid or 'hybridoma" which is both immortal and capable of producing the genetically coded antibody of the B cell. The hybrids thus formed are segregated into single genetic strains by dilution and regrowth, and each strain thus represents a single genetic line. They therefore produce immunoactive antibodies against a desired antigen which are assured to be homogenous, and which antibodies, referencing their pure genetic parentage, are called "monoclonal". Hybridoma technology has to this time been largely focused of fusion murine lines, but human-human hybridomas, and human-murine hybridomas have been prepared as well.

Polyclonal, or, much more preferably, monoclonal, antibodies have a variety of useful properties similar to those of the present invention. For example, they can be used as specific immunoprecipitating reagents to detect the presence

of the antigen which elicited the initial formation of the B cell genome by coupling this reaction with suitable detection techniques such as labeling with radioisotopes or with enzymes capable of assay (RIA, EMIT, and ELISA). These antibodies are thus the foundation of diagnostic tests for these antigenic substances. In another important use, such antibodies can be directly injected into subjects suffering from an attack by a substance or organism containing the antigen in question to combat this attack. This process is currently in its experimental stages, but its potential is clearly seen. Third, whole body diagnosis and treatment is made possible because injected antibodies are directed to specific target disease tissues which have proper antigenic surfaces, and can be used either to determine the presence of the disease by carrying with them a suitable label, or to attack the diseased tissue by carrying a suitable drug.

Monoclonal antibodies produced by hybridomas, while theoretically effective as suggested above and clearly preferable to polyclonals because of their specificity, suffer from certain disadvantages. First, they tend to be contaminated with other proteins and cellular materials of hybridoma, (and, therefore, mammalian) origin. This is particularly serious because of the nature of the cells used to immortalize the hybridoma cell lines, which are, of course, themselves malignant. These cells contain additional materials, notably nucleic acid fragments, but protein fragments as well, which are capable of enhancing, causing, or mediating carcinogic responses. Second, hybridoma lines producing monoclonals tend to become unstable after several generations of production and to alter the structure of antibody produced. The cell line genome appears to alter itself in response to stimuli whose nature is not currently known, and this alteration results production of incorrect sequences. Third, both hybridoma and B cells inevitably produce certain antibodies in glycosylated form which, under some circumstances, is undesirable. Fourth, production of both monoclonals and poly-

clonals is relatively expensive. Fifth, and perhaps most important, production by current techniques (either by hybridoma or by B cell response) does not permit manipulation of the genome so as to produce antibodies with more effective design components than those normally elicited in response to antigens from the mature B cell in situ. The antibodies of the present invention do not suffer from the foregoing drawbacks, and, furthermore, offer the opportunity to provide molecules of superior design.

A.2 *General Structure Characteristics*

The general structure of antibody molecules in mammalian systems is now well understood. They are composed of two identical light polypeptide chains of molecular weight approximately 23,000 daltons, and two identical heavy chains of molecular weight 53,000-70,000. The four chains are joined by disulfide bonds in a "Y" configuration wherein the light chains bracket the heavy chains starting at the mouth of the Y and continuing through the divergent region as shown in figure 1. The "branch" portion, as there indicated, is designated the Fab region. Heavy chains are classified as gamma, mu, alpha, delta, or epsilon, with some subclasses among them, and the nature of this chain, as it has a long constant region, determines the "class" of the antibody as IgG, IgM, IgA, IgD, or IgE. Light chains are classified as either kappa or lambda. Each heavy chain class can be prepared with either kappa or lambda light chain. The light and heavy chains are covalently bonded to each other, and the "tail" portions of the two heavy chains are bonded to each other by covalent disulfide linkages when the antibodies are generated either by hybridomas or by B cells. However, if non-covalent association of the chains can be effected in the correct geometry, the aggregate will still be capable of reaction with antigen.

The amino acid sequence runs from the N-terminal end at the top of the Y to the C-terminal end at the bottom of each

chain. At the N-terminal end is a variable region which is specific for the antigen which elicited it, and is approximately 100 amico acids in length, there being slight variations between light and heavy chain and from antibody to antibody. The variable region is linked in each chain to a constant region which extends the remaining length of the chain through a linking sequence known currently as the "C" region in the light chain, comprising about 12 amino acids, and as a combination of "D" region and "J" region in the heavy chain, comprising around 25 amino acids.

The remaining portions of the chain are referred to as constant regions and within a particular class appear not to vary, at least very much, with the specificity of the antibody (i.e., the antigen eliciting it).

At present there are five known major classes of constant regions which determine the class of the immunoglobulin molecule (IgG, IgM, IgA, IgD, and IgE corresponding to γ, μ, α, δ, and ε heavy chain constant regions). The constant region or class seems to determine the effector function of the antibody i.e., activation of complement, release of histamine, etc. As mentioned above, the variable region determines the antigen with which it will react.

B. *Recombinant DNA Technology*

Recombinant DNA technology has reached sufficient sophistication that it includes a repertoire of techniques for cloning and expression of gene sequences. Various DNA sequences can be recombined with some facility, creating new DNA entities capable of producing heterologous protein product in transformed microbes and cell cultures. The general means and methods for the *in vitro* ligation of various blunt ended or "sticky" ended fragments of DNA, of producing expression vectors, and of transforming particular organisms, to direct synthesis of desired product are in hand. However, on an individual product basis, the pathway remains tortuous and unchartable in advance and the science

has not advanced to a stage where predictions of success can to made. Indeed, those who portend successful results without the underlying experimental basis, do so at considerable risk of inoperability.

DNA recombination of the essential elements, i.e., an origin of replication, one or more phenotypic selection characteristics, expression control sequence, heterologous gene insert and remainder vector, generally is performed outside the host cell. The resulting recombinant replicable expression vector, or plasmid, is introduced into cells by transformation and large quantities of the recombinant vehicle is obtained by growing the transformant. Where the gene is properly inserted with reference to portions which govern the transcription and translation of the encoded DNA message, the resulting expression vector is useful to produce the polypeptide sequence for which the inserted gene codes, a process referred to as "expression." The resulting product may be obtained by lysis, if necessary, of the host cell and recovery of the product by appropriate purifications from other proteins.

In practice, the use of recombinant DNA technology can express entirely heterologous polypeptides—so-called direct expression—or alternatively may express a heterologous polypeptide fused to a portion of the amino acid sequence of a homologous polypeptide. In the latter cases, the intended bioactive product is sometimes rendered bioinactive within the fused, homologous/heterologous polypeptide until it is cleaved in an extracellular environment.

The art of maintaining cell or tissue cultures as well as microbial systems for studying genetics and cell physiology is well established. Means and methods are available for maintaining permanent cell lines, prepared by successive serial transfers from isolated cells. For use in research, such cell lines are maintained on a solid support in liquid medium,

or by growth in suspension containing support nutriments. Scale-up for large preparations seems to pose only mechanical problems.

Summary of the Invention

The invention relates to antibodies formed by recombinant techniques using suitable host cell cultures. These antibodies can be prepared in pure form, and, further, can be manipulated at the genomic level to produce hybrids of variants which draw their homology from species which differ from each other. Thus, there are a number of "types" of antibodies encompassed by the invention. First, antibodies are produced using recombinant techniques which mimic the amino acid sequence of naturally occuring antibodies produced by either mammalian B cells *in situ*, or by B cells fused with suitable tumor immortalizing lines, i.e., hybridomas. Second, the methods of this invention produce, and the invention is directed to, antibodies which comprise light chains whose amino acid sequence mimics that of one naturally occuring antibody, and heavy chains whose amino acid sequence mimics the heavy chain of another. The antibody chains so mimicked may be of different species, i.e. "composite antibodies" especially "divalent" antibodies. Third, by genetic manipulation, "hybrid" antibodies can be formed wherein variable regions correspond to the amino acid sequence from one mammalian model system, whereas the constant region mimics the amino acid sequence of another. Again, the derivation of these two mimicked sequences may be from different species. Fourth, antibodies may be produced which include only the "Fab" region of an antibody molecule i.e. the branches of the antibody "Y". These Fab fragments may also be composite—i.e., one chain derived from one model antibody and the other from another, each of different species, or hybrid, where the constant and variable sequence patterns may be of different origin. Finally, either the light chain or heavy chain alone, or active portions thereof,

produced by recombinant techniques are included in the invention.

In other aspects, the invention is directed to DNA which encodes the aforementioned antibodies and portions thereof, as well as expression vectors or plasmids capable of effecting the production of such antibodies in suitable host cells. It includes the host cells and cell cultures which result from transformation with these vectors. Finally, the invention is directed to methods of producing these antibodies, and the DNA sequences, plasmids, and transformed cells intermediate to them.

Brief Description of the Drawings

Figure 1 is a representation of the general structure of mammalian antibodies.

Figure 2 shows the detailed sequence of the cDNA insert of pK17G04 which encodes kappa anti CEA chain.

Figure 3 shows the coding sequence of the fragment shown in Figure 2, along with the corresponding amino acid sequence.

Figure 4 shows this DNA fragment encoding gamma anti CEA chain.

Figure 5 shows the corresponding amino acid sequence encoded by the fragment in Figure 4.

Figures 6 and 7 outline the construction of expression vectors for kappa and gamma anti CEA respectively.

Detailed Description

A. Definitions

As used herein, "antibodies" refers to tetramers which have specific immunoprecipitating activity comprising two light chains of approximately 25kD and two heavy chains of approximately 50-70kD, aggregated in the "Y" configuration of figure 1, with or without covalent linkage between them.

"Mammalian antibodies" refers to antibodies wherein the amino acid sequences of the chains are homologous with those sequences found in antibodies produced by mammalian systems, either in situ, or in hybridomas. These antibodies mimic antibodies which are otherwise capable of being generated, although in impure form, in these traditional systems.

"Composite antibodies" refer to antibodies wherein chains are separately homologous with referenced mammalian antibody chains. For example, while the light chains are homologous to sequences found in one type of mammalian derived antibodies, the heavy chains might mimic another. However, in a preferred embodiment of composite antibody, "divalent" antibodies result. In this embodiment, one pair of heavy chain is homologous to antibodies raised against one antigen, while the other pair of heavy and light chain is homologous to those raised against another antigen. This results in the property of "divalence" i.e., ability to bind two antigens simultaneously.

"Hybrid antibodies" refers to those antibodies wherein one portion of each of the amino acid sequences of heavy and light chains is homologous to corresponding sequences in antibodies derived from a particular species or belonging to a particular class, while the remaining segment of the chains is homologous to corresponding sequences in another. Typically, in these hybrid antibodies, the variable region of both light and heavy chains mimics the variable regions of antibodies derived from one species of mammals, while the constant portions are homologous to the sequences in antibodies derived from another. However, the definition is not limited to this particular example. It includes any antibody in which either or both of the heavy or light chains are made up from combinations of sequences mimicking the sequences in antibodies of different sources, whether these sources be differing classes, differing antigen responses, or differing species of origin.

"Fab region" refers to those portions of the chains which are roughly equivalent or analogous to the sequences which comprise the Y branch portions of the heavy chain and the light chain in its entirety. "Fab region" includes aggregates of one heavy and the light chain, as well as tetramers which correspond to the two branch segments of the antibody Y, whether any of the above are covalently or non-covalently aggregated, so long as the aggregation is capable of selectively reacting with a particular antigen or antigen family.

"Fab region" has the same subsets according to the definition of the present invention as does the general term "antibodies". Thus, "mammalian Fab region", "composite Fab region", and "hybrid Fab region" are defined analogously to the corresponding definitions set forth in the previous paragraphs for the various types of antibodies.

Individual heavy or light chains may of course be either "mammalian" or "hybrid" in accordance with the above. As will become apparent from the detailed description of the invention, it is possible, using the techniques disclosed to prepare other combinations of the four-peptide chain aggregates, besides those specifically defined such as composite antibodies containing hybrid light and mammalian heavy chains, composite Fab regions containing hybrid Fab regions of heavy chains associated with mammalian light chains, and so forth.

"Expression vector" includes vectors which are capable of expressing DNA sequences contained therein, i.e., the coding sequences are operably linked to other sequences capable of effecting their expression. It is implied, although not always explicitly stated, that these expression vectors must be replicable in the host organisms either as episomes or as an integral part of the chromosomal DNA. Clearly a lack of replicability would render them effectively inoperable. A useful, but not a necessary, element of an effective expression vector is a marker encoding sequence—i.e. sequences en-

coding a protein which results in a phenotypic property (e.g. tetracycline resistance) of the cells containing them which permits those cells to be readily identified. In sum, "expression vector" is given a functional definition, and any DNA sequence which is capable of effecting expression of a specified contained DNA code is included in this term, as it is applied to the specified sequence. As at present, such vectors are frequently in the form of plasmids, plasmic and expression vector are often used interchangeably. However, the invention is intended to include such other forms of expression vectors which serve equivalent functions and which may, from time to time become known in the art.

"Recombinant host cells" refers to cells which have been transformed with vectors constructed using recombinant DNA techniques. As defined herein, the antibody or modification thereof produced by a recombinant host cell is by virtue of this transformation, rather than in such lesser amounts, or more commonly, in such less than detectable amounts, as would be produced by the untransformed host.

In descriptions of processes for isolation of antibodies from recombinant hosts, the terms "cell" and "cell culture" are used interchangeably to denote the source of antibody unless it is clearly specified otherwise. In other words, recovery of antibody from the "cells" may mean either from spun down whole cells, or from the cell culture containing both the medium and the suspended cells.

3. *Host Cell Cultures and Vectors*

The vectors and methods disclosed herein are suitable for use in host cells over a wide range of prokaryotic and eukaryotic organisms.

In general, of course, prokaryotes are preferred for cloning of DNA sequences in constructing the vectors useful in the invention. For example, *E. coli* K12 strain 294 (ATCC No. 31446) is particularly useful. Other microbial strains which

may be used include *E. coli* strains such as *E. coli* 8, and *E. coli* 1776 (ATTC No. 31537). These examples are, of course, intended to be illustrative rather than limiting.

Prokaryotes may also be used for expression. The aforementioned strains, as well as *E. coli* W3110 (Fλ, prototrophic, ATTC No. 27325), bacilli such as *Bacillus subtilus*, and other entercoacteriaceae such as *Salmonella typhimurium* or *Serratia marcesans*, and various *Pseudomonas* species may be used.

In general, plasmid vectors containing replicon and control sequences which are derived from species compatible with the host cell are used in connection with these hosts. The vector ordinarily carries a replication site, as well as marking sequences which are capable of providing phenotypic selection in transformed cells. For example, *E. coli* is typically transformed using p8R322, a plasmic derived from an *E. coli* species (Bolivar, et al., *Gene* 2: 95 (1977)). pBR322 contains genes for ampicillin and tetracycline resistance and thus provides easy means for identifying transformed cells. The pBR322 plasmid, or other microbial plasmid must also contain, or be modified to contain, promoters which can be used by the microbial organism for expression of its own proteins. Those promoters most commonly used in recombinant DNA construction include the β-lactamase (penicillinase) and lactose promoter systems (Chang et al, *Nature*, 275: 615 (1978); Itakura, et al, *Science*, 198: 1056 (1977); (Sceddel, et al *Nature* 981: 544 (1979)) and a tryptophan (trp) promoter system (Goeddel, et al, *Nucleic Acids Res.*, 8: 4057 (1980); EPO Appl Publ No. 0036776). While these are the most commonly used, other microbial promoters have been discovered and utilized, and details concerning their nucleotide sequences have been published, enabling a skilled worker to ligate them functionally with plasmid vectors Siebenlist, et al. *Cell* 26: 269 1980.

In addition to prokaryates, eukaryotic microbes, such as yeast cultures may also be used. *Saccharomyces cerevistae*, or common baker's yeast is the most commonly used among eukaryotic microorganisms, although a number of other strains are commonly available. For expression in *Saccharomyces*, the plasmid YRp7, for example, (Stinchcomo, et al, *Nature*, 282: 39 (1979); Kingsman et al, *Gene*, 7: 141 (1979); Tschemper, et al, *Gene*, 10: 157 (1980)) is commonly used. This plasmid already contains the *trpl* gene which provides a selection marker for a mutant strain of yeast lacking the ability to grow in tryptophan, for example ATCC No. 44076 or PEP4-1: (Jones, *Genetics*, 85: 12 (1977)). The presence of the *trpl* lesion as a characteristic of the yeast host cell genome then provides an effective environment for detecting transformation by growth in the absence of tryptophan.

Suitable promoting sequences in yeast vectors include the promoters for 3-phosphoglycerate kinase (Hitzeman, et al., *J. Biol. Chem.*, 255: 2073 (1980)) or other glycolytic enzymes (Hess, et al, *J. adv. Enzyme Reg.*, 7: 149 (1968); Holland, et al, Biochemistry, 17: 4900 (1978)), such as enolase glyceraldehydes-3-phosphate dehydrogenase, hexokinase, pyruvate decarboxylase, phosphofructokinase, glucose-δ-phosphate isomerase, 3-phosphoglycerate mutase, pyruvate kinase, triosephosphate isomerase, phosphoglusoce isomerase, and glucokinase. In constructing suitable expression plasmids, the termination sequences associated with these genes are also ligated into the expression vector 3 of the sequence desired to be expressed to provide polyadenylation of the mRNA and termination. Other promoters, which have the additional advantage of transcription controlled by growth conditions are the promoter regions for alcohol dehydrogenase 2, isocytochrome C, acid phosphatase degradative enzymes associated with nitrogen metapolism, and the aforementioned glyceraldehyde-3-phosphate dehydrogenase, and enzymes responsible for maltose and galactose utilization (Holland, ioid.). Any plasmid vector containing yeast-

compatible promoter, origin of replication and termination sequences is suitable.

In addition to microorganisms, cultures of cells derived from multicellular organisms may also be used as hosts. In principle, any such cell culture is workable, whether from vertebrate or invertebrate culture. However interest has been greatest in vertebrate cells, and propogation of vertebrate cells in culture (tissue culture) has become a routine procedure in recent years (*Tissue Culture*, Academic Press, Kruse end Patterson, editors (1973)]. Examples of such useful host cell lines are VERO and HeLa cells, Chinese hamster ovary (CHO) cell lines, and W138, BHK, COS-7 and MDCK cell lines. Expression vectors for such cells ordinarily include (if necessary) an origin of replication, a promoter located in front of the gene to be expressed, along with any necessary ribosome binding sites, RNA splice sites, polyadenylation site, and transcriptional terminator sequences.

For use in mammalian cells, the control functions on the expression vectors are often provided by viral material. For example, commonly used promoters are derived from polyoma, Adenovirus 2, and most frequently Simian Virus 40 (SV40). The early and late promoters of SV40 virus are particularly useful because both are obtained easily from the virus as a fragment which also contains the SV40 viral origin of replication (Fiers, et al. *Nature*, 273: 113 (1978)) incorporated herein by reference. Smaller or larger SV40 fragments may also be used, provided there is include [*sic*] the approximately 250 bp sequence extending from the Hind III site toward the Bgl I site located in the viral origin of replication [*sic*]. Further, it is also possible, and often desirable, to utilize promoter or control sequences normally associated with the desired gene sequence, provided such control sequences are compatible with the host cell systems.

An origin of replication may be provided either by construction of the vector to include an exogenous origin,

such as may be derived from SV40 or other viral (e.g. Polyoma, Adeno, VSV, BPV, etc.) source, or may be provided by the host cell chromosomal replication mechanism. If the vector is integrated into the host cell chromosome, the latter is often sufficient.

It will be understood that this invention, although described herein in terns of a preferred embodiment, should not be construed as limited to those host cells, vectors and expression systems exemplified.

C. *Methods Employed*

C.1 *Transformation*:

If cells without formidable cell wall barriers are used as host cells, transfection is carried out by the calcium phosphate precipitation method as described by Graham and Van der Eb, *Virology*, 52: 546 (1978). However, other methods for introducing DNA into cells such as by nuclear injection or by protoplast fusion may also be used.

If prokaryotic cells or cells which contain substantial cell wall constructions are used, the preferred method of transfection is calcium treatment using calcium chloride as described by Cohen, F.N. et al *Proc. Natl. Acad. Sci.* (USA), 69: 2110 (1972).

C.2 *Vector Construction*

Construction of suitable vectors containing the desired coding and control sequences employ standard ligation techniques. Isolated plasmids or DNA fragments are cleaved, tailored, and religated in the form desired to form the plasmids required. The methods employed are not dependent on the DNA source, or intended host.

Cleavage is performed by treating with restriction enzyme, (or enzymes) in suitable buffer. In general, about 1 μg plasmid or DNA fragments is used with about 1 unit of enzyme in about 20 μl of buffer solution. (Appropriate buffers and

substrate amounts for particular restriction enzymes are specified by the manufacturer. Incubation times of about 1 hour at 37°C are workable. After incubations, protein is removed by extraction with phenol and chloroform, and the nucleic acid is recovered from the aqueous fraction by precipitation with ethanol.

If blunt ends are required, the preparation is treated for 15 minutes at 15° with 10 units of *E. coli* DNA Polymerase 1 (Klenow), phenol-chloroform extracted, and ethanol precipitated.

Size separation of the cleaved fragments is performed using 6 percent polyacrylamide gel described by Goeddel, D., et al, *Nucleic Acids Res.* 8: 4057 (1980) incorporated herein by reference.

For ligation, approximately equimolar amounts of the desired components, suitably end tailored to provide correct matching are treated with about 10 units T4 DNA ligase per 0.5 μg DNA. (When cleaved vectors are used as components, it may be useful to prevent religation of the cleaved vector by pretreatment with bacterial alkaline phosphatase.)

In the examples described below correct ligations for plasmid construction are confirmed by transforming *E. coli* K12 strain 294 (ATCC 31446) with the ligation mixture. Successful transformants were selected by ampicillin or tetracycline resistance depending on the mode of plasmid construction. Plasmids from the transformants were then prepared, analyzed by restriction and/or sequenced by the method of Messing, et al, *Nucleic Acids Res.*, 9:309 (1981) or by the method of Maxam, et al, *Methods in Enzymology*, 65: 499 (1980).

D. *Outline of Procedures*

D.1 *Mammalian Antibodies*

The first type of antibody which forms a part of this invention, and is prepared by the methods thereof, is "mammalian antibody" one wherein the heavy and light chains mimic the amino acid sequences of an antibody otherwise produced by a mature mammalian 8 lymphocyte either *in situ* or when fused with an immortalized cell as part of a hydridoma culture. In outline, these antibodies are produced as follows:

Messenger RNA coding for heavy or light chain is isolated from a suitable source, either mature B cells or a hydridoma culture, employing standard techniques or RNA isolation, and the use of oligo—dT cellulose chromatography to segregate the poly-A mRNA. The poly-A mRNA may, further, be fractionated to obtain sequences of sufficient size to code for the amino acid sequences in the light or heavy chain of the desired antibody as the case may be.

A cDNA library is then prepared from the mixture of mRNA using a suitable primer, preferably a nucleic acid sequence which is characteristic of the desired cDNA. Such a primer may be hypothesized and synthesized based on the amino acid sequence of the antibody if the sequence is known. In the alternative cDNA from unfractionated poly-A mRNA from a cell line producing the desired antibody or poly-dT may also be used. The resulting cDNA is optionally size fractionated on polyacrylamide gel and then extended with, for example, dC residues for annealing with pBR322 or other suitable cloning vector which has been cleaved by a suitable restriction enzyme, such as Pst I, and extended with dG residues. Alternative means of forming cloning vectors containing the cDNA using other tails and other cloning vector remainder may, of course, also be used but the foregoing is a standard and preferable choice. A suitable host

cell strain, typically *E. coli*, is transformed with the annealed cloning vectors, and the successful transformants identified by means of, for example, tetracycline resistance or other phenotypic characteristic residing on the cloning vector plasmid.

Successful transformants are picked and transferred to microtiter dishes or other support for further growth and preservation. Nitrocellulose filter imprints of these growing cultures are then probed with suitable nucleotide sequences containing bases known to be complementary to desired sequences in the cDNA. Several types of probe may be used, preferably synthetic single stranded DNA sequences labeled by kinasing with ATP^{32}. The cells fixes to the nitrocellulose filter are lysed, the DNA denatured, and then fixed before reaction with kinased probe. Clones which successfully hybridize are detected by contact with a photoplate, then plasmids from the growing colonies isolated and sequenced by means known in the art to verify that the desired portions of the gene are present.

The desired gene fragments are excised and tailored to assure appropriate reading frame with the control segments when inserted into suitable expression vectors. Typically, nucleotides are added to the 5' end to include a start signal and a suitably positioned restriction endonuclease site.

The tailored gene sequence is then positioned in a vector which contains a promoter in reading frame with the gene and compatible with the proposed host cell. A number of plasmids such as those described in U.S. Pat. Application Ser. No. 307473; 291892; and 305657, have been described which already contain the appropriate promoters, control sequences, ribosome binding sites, and transcription termination sites, as well as convenient markers.

In the present invention, the gene coding for the light chain and that coding for the heavy chain are recovered separately by the procedures outlined above. Thus they may be inserted

into separate expression plasmids, or in tandem in the same plasmid, so long as each is under suitable promoter and translation control.

The expression vectors constructed above are then used to transform suitable cells. The light and heavy chains may be transformed into separate cell cultures, either of the same or of differing species; separate plasmids for light and heavy chain may be used to co-transform a single cell culture, or, finally, a single expression plasmid containing both genes and capable of expressing the genes for both light and heavy chain may be transformed into a single cell culture.

Regardless of which of the three forgoing options is chosen, the cells are grown under conditions appropriate to the production of the desired protein. Such conditions are primarily mandated by the type of promoter and control systems used in the expression vector, rather than by the nature of the desired protein. The protein thus produced is then recovered from the cell culture by methods known in the art, but choice of which is necessarily dependent on the form in which the protein is expressed. For example, it is common for mature heterologous proteins expressed in *E. coli* to be deposited within the cells as insoluble particles which require cell lysis and solubilization in denaturant to permit recovery. On the other hand, proteins under proper synthesis circumstances, in yeast and bacterial strains, can be secreted into the medium, or recovered by less drastic procedures. Tissue culture cells as hosts also appear, in general, to permit reasonably facile recovery of heterologous proteins.

When heavy and light chain are coexpressed in the same host, the isolation procedure is designed so as to recover reconstituted antibody. This is done by providing mild denaturing/renaturing conditions so as to permit such assembly. Typically, extraction in about 5 - 9M area in the presence of reducing agent, followed by dialysis into dilute buffer in the presence of air provides these conditions.

If the heavy and light chains are prepared in separate cell cultures, additional steps are required to secure the reconstitution of the two chains. This recombination can be effected as follows:

D.2 *Composite Antibodies*

The foregoing procedure which describes the recombinant production of mammalian antibodies is employed with some modifications to construct the remaining types of antibodies encompassed by the present invention. To prepare the embodiment of composite antibodies wherein the homology of the chains corresponds to the sequences of antibodies of different origins it is of course, only necessary to prepare the heavy and light chains in separate cultures and reassemble them as desired.

For example, in order to make a murine light chain-human heavy chain composite antibody, a suitable murine source for the mRNA used as a template for the light chain clone would comprise one of the many available murine-murine hybridomas, or even a murine-human hybridoma wherein the B cell is murine derived and the myeloma from human beings. The heavy chain would need to be derived from a human-human hybridoma, or at least one in which the B cell was of human origin in order to provide the mRNA for the heavy chain. It is clear that such composites can be assembled using the methods of the invention almost at will, and are limited only by available sources of mRNA suitable for use as templates for the respective chains. All other features of the process are similar to those described above.

Divalent antibodies are particularly useful as they are capable of simultaneous reaction with more than one antigen. Again, heavy and light chaines [*sic*] corresponding, in the prefered embodiment to the chains of antibodies of the same origin are prepared in separate cultures. Two such sets are prepared. The separate preparation of heavy and light chains

prevents premature assembly of the tetramer. Subsequent mixing of the four separately prepared peptides then permits assembly into the desired tetramers. While random aggregation will lead to the formation of some byproduct mammalian antibodies, approximately half of the product in which homologously desired light and heavy chains are bound to each other is the desired divalent antibody.

D.3 *Hybrid Antibodies*

For construction of hybrid antibodies (wherein, for example, the variable sequences are separately derived from the constant sequences) the procedures of paragraph D.1 are again applicable with appropriate additions and modifications. A preferred procedure is to recover desired portions of the genes encoding for parts of the heavy and light chains from suitable, differing sources and then to religate these fragments using restriction endonucleases to reconstruct the gene coding for each chain.

For example, in a particularly uncomplex preferred hybrid construction, portions of the heavy chain gene and of the light chain gene which encode the variable sequences of antibodies produced by a murine hybridoma culture are recovered and cloned from the murine culture and gene fragments encoding the contant [*sic*] regions of the heavy and light chains for human antibodies are recovered and cloned from for example, a human-human hybridoma. Suitable restriction enzymes may then be used to ligate the variable portions of the mouse gene to the constant regions of the human gene for each of the two chains. The hybrid chains are produced as set forth in D.1, aggregated and used in the same manner as the non-hybrid forms.

D.4 *Fab Region*

Similarly, it is not necessary to include the entire gene for the heavy chain portion. All of the aforementioned variations can be superimposed on a procedure for Fab region pro-

duction and the overall procedure differs only in that that portion of the heavy chain coding only for the first approximately 220 amino acids of the heavy chain is employed in the expression vector.

E. *Specific Examples of Preferred Embodiments*

The invention has been described above in general terms and there follow several specific examples of embodiments of this invention which set forth details of experimental procedure in producing the desired antibodies. Example E.1 sets forth the general procedure for preparing anti CEA antibody, a "mammalian antibody". Example E.3 sets forth the procedure for tailoring the heavy or light chain so that the variable and constant regions may be derived from different sources. When combined with the procedure in example E.1, this exemplifies the production of the hybrid antibodies. Example E.4 sets forth the method of obtaining a shortened heavy chain genome which permits the production of the Fab regions. Composite antibodies and Fab regions differ only in the choice source materials for heavy and light chains, as set forth in E.4.

The examples set forth below are for illustrative purposes and do not limit the scope of the invention.

E.1 *Preparation of Expression Vectors for Murine anti-CEA Antibody Chains and Peptide Synthesis*

Carcinoembryonic antigen (CEA) is associated with the surface of tumor cells in post-natal mammals. Antibodies which bind to it (anti-CEA) antibodies) [*sic*] are useful in detection and treatment of certain mammalian tumors which appear to support CEA at their surfaces. A mouse hybridoma cell line SP_2-014 Ag which secretes anti-CEA antibodies has been prepared as described by ___.

E.1.1 *Isolation of Messenger RNA for Anti CEA-Kappa and Gamma Chains*

Total RNA from SP_2-014Ag cells was extracted essentially as reported by Lynch et al, ___. Cells were pelleted by centrifugation and approximately 1 g portions of pellet resuspended in 10 ml of 10 mM NaCl, 10 mM Tris HCl (pH 7.4), 1.5 mM $MgC1_2$. The resuspended cells were lysed by addition of non-ionic detergent NP-40 to a final concentration of 1 percent, nuclei removed by centrifugation and the supernatant extracted twice with ___ml portions of phenol (redistilled)/chlroform: isoamyl alcohol ___:___ at 4°C. The aqueous phase was made O.2 M in NaCl and total RNA was precipitated by addition of two volumes of 100 percent ethanol and overnight storage at -20°C. After centrifugation, polyA mRNA was purified from total RNA by oligo-dT cellulose chromatography as described by ___. 10-15 mg of total RNA containing -2 percent polyA mRNA was obtained from 1g cells.

E.1.2 *Preparation of Oligo-dT Primed Colony Library Containing Kappa and Gamma DNA Sequences*

5 μg of the unfractionated polyA mRNA prepared in paragraph E.1.1 was used as template for oligo-dT primed preparation of double-stranded (ds) cDNA by standard procedures as described by Goeddel et al., *Nature* 281: 544 (1979) and Wickens et al., *J. Biol. Chem.* 253: 2483 (1978) incorporated herein by reference. The cDNA was size fractionated by a percent polyacrylamide gel electrophoresis and 124 ng of ds cDNA greater than 600 base pairs in length was recovered by electruelution. A 20 ng portion of ds dDNA was extended with deoxy C residues using terminal deoxynucleotidyl transferase as described in Chang et al., *Nature* 275: 617 (1978) incorporated herein by reference, and annealed with 200 ng of the plasmid pBR322 (Bolivar et al., *Gene* 2: 95 (1977)): which had been cleaved with Pst I and tailed with deoxy G. Each annealed mixture was then transformed into *E. coli* K12

strain 294 (ATCC No. 31446). Approximately 7500 ampicillin sensitive, tetracycline resistant transformants were obtained.

E.1.3 *Preparation of Synthetic DNA Kappa and Gamma DNA Screening Probes*

The 14mer, 3' AGGTAGAAGGGTGG 5' complementary to the coding sequence of constant region for mouse MOPC21 kappa chain which begins 25 basepairs 3' of the variable region DNA sequence was used as kappa probe. A 15 mer, 3' GACCCTACGGACCAG 5', complementary to a coding sequence located 72 basepairs 3' of the variable region DNA sequence for mouse MOPC21 gamma chain was used to probe gamma.

Both probes were synthesized by the phospnotriester method described in German Offenlegungschrift 2644432, incorporated herein by reference, and made radioactive by kinasing as follows: 250 ng of deoxyoligonucleotide were combined in 25 µl of 60 mM Tris HCl (pH 8), 10 mM $MgCl_2$, 15 mM beta-mercaptoethanol, and 100 µCi (γ-^{32}P) ATP (Amersham, 5000 Ci/mMole). 5 units of T4 polynucleotide kinase were added and the reaction was allowed to proceed at 37°C for 30 minutes and terminated by addition of EDTA to 20mM.

E.1.4 *Screening of Oligo dT Primed Colony Library for Kappa or Gamma Sequences*

-2000 colonies of the transformants prepared as described in paragraph E.1.2 were individually inoculated into wells of microtitre dishes containing L8 (Miller, Experiments in Molecular Genetics, p. 431-3, Cold Spring Harbor Lab., Cold Spring Harbor, New York (1972)) 5µg/ml tetricycline and stored at -20°C after addition of DMSO to 7 percent. Individual colonies from this library were transferred to duplicate sets of Scleicher and Schuell 8A85/20 nitrocellulose filters and grown on agar plates containing L8+5 µg/ml tetracycline. After -10 hours growth at 37°C the colony filters were

transferred to agar plates containing L8+5 μg/ml tetracycline and 12.5 μg/ml chloramphenical and reincubated overnight at 37°C. The DNA from each colony was then denatured and fixed to the filter by a modification of the Grunstein-Hogness procedure as described in Grunstein et al., *Proc. Nat'l Acad. U.S.A.* 72; 3961 (1975), incorporated herein by reference. Each filter was floated for 3 minutes on 0.6N NaOH,1.5 M NaCl to lyse the colonies and denature the DNA then neutralized by floating for 15' on 3 M NaCl, 0.5 M Tris HCl (pH 7.5). The filters were then floated for an additional 15 minutes on 2XSSC, and subsequently baked for 2 hours in an 80°C vacuum oven. The filters were prehybridized for -2 hours at room temperature in 0.9 M NaCl 1x Denhardts, 100 mM Tris HCl (pH 7.5), 5 mM Na-EDTA, 1 mM ATP, 1 M sodium phosphate (dibasic), 1 mM sodium pyrophosphate, 0.5 percent NP-40, and 200 μg/ml *E. Coli* t-RNA and hybridized in the same solution overnight, essentially as described by Wallace *et al. Nucleic Acids Research* 9: 879 (1981) using -40x10^6 cpm of either the kinased kappa or gamma probe described above.

After extensive washing at 37°C in 6X SSC, 0.1 percent SDS, the filters were exposed to Kodak XR-5 X-ray film with DuPont Lightning-Plus intensifying screens for 16-24 hours at -80°C. Approximately 20 colonies which hybridized with kappa probe and 20 which hybridized with gamma probe were found.

E.1.5 *Characterization of Colonies Indicating Positive Hybridization for Kappa DNA Sequence*

Plasmid DNAs isolated from several different transformed colonies which hybridized to kappa probe by the rapid miniscreen procedure of Birnboim et al., *Nucleic Acids Research*, 7: 1513 (1979), incorporated herein by reference, were cleaved with PSt I and fractionated on polyacrylamide gel. This analysis demonstrated that a number of plasmid DNAs contained cDNA inserts large enough to encode full

length kappa chain. The complete nucleotide sequence one of these plasmids (pK17G4) cDNA insert was determined by the dideoxynucleotide chain termination method as described by Smith, *Methods Enzymol. 65*, 560 (1980) incorporated herein by reference after subcloning restriction endonuclease cleavage fragments into M13 vectors (Messing et al., *Nucleus Acids Research* 9: 309 (1981), Figure 2 shows the nucleotide sequence of the cDNA insert of pK17G4 and Figure 3 shows the gene sequence with the corresponding amino acid sequence. Thus, the entire coding region of mouse anti-CEA kappa chain was isolated on this one large DNA fragment. The nucleotide sequence of the kappa probe includes nucleotides 377 through 390 of the pK17G4 insert which corresponds perfectly with the first 23 N-terminal amino acids of mature mouse anti-CEA kappa chain (as determined by amino acid sequence analysis of purified mouse anti-CEA kappa chain). The coding region of pK17G4 consists of 27 basepairs or 9 amino acids of the presequence and 648 basepairs or 226 amino acids of the mature protein. The mature protein has a variable region of 107 amino acids, a J1 joining region of 12 amino acids on a constant region of 107 amino acids. The stop codon after the C terminal amino acid 215 begins the 212 basepairs of 3' untranslated sequence up to the polyA addition.

E.1.6 *Characterization of Colonies Indicating Positive Hybridization for Gamma 1 DNA Sequence*

Plasmid DNA isolated from several transformants positive for hybridization with the gamma 1 prove was subjected to PSt I restriction endonuclease analysis as described in E.1.5. Plasmid DNAs demonstrating the largest cDNA insert fragments were selected for further study. Nucleotide sequence information for mouse gamma 1, shows an NcoI restrictiction endonuclease cleavage site near the junction between variable and constant region. Selected plasmid DNAs were digested with both PstI and NcoI and sized on polyacrylamide. This

analysis allowed identification of a number of plasmid DNAs that contain NcoI restriction endonuclease sites, although none that demonstrate cDNA insert fragments large enough to encode the entire coding region of mouse anti-CEA gamma 1 chain. Figure 4 presents the entire nucleotide sequence of mouse anti-CEA gamma 1 chain (as determined by dide oxynucleotide chain termination method of Smith, *Methods Enzymol*, 65:, 560 (1980)), and Figure 5 includes the translated sequence. In one plasmid isolated, p γ298 cDNA insert of about 1300 bp contains sequence information for the 5' untranslated region, the signal sequence and the N-terminal portion of gamma-1. Because p γ298 did not encode the C-terminal sequence for mouse anti-CEA gamma 1 chain, plasmid DNA was isolated from other colonies and screened and PstI and NcoI. The C-terminal region of the cDNA insert of Pγ11, one of these isolated, was sequenced and shown to contain the stop codon 3' untranslated sequence and that portion of the coding sequence missing from p γ298.

The nucleotide sequence of the gamma 1 probe includes nucleotides 528 through 542 of the gamma sequence shown in Figure 3 which corresponds perfectly to the first 16 N-terminal amino acids of mature mouse anti-CEA gamma 1 chain (as determined by amino acid sequence analysis of purified mouse anti-CEA gamma 1 chain.). The coding region consists of 57 basepairs or 19 amino acids of presequences and 1346 basepairs or 447 amino acids of mature protein. The mature protein has a variable region of 110 amino acids, a J4 joining region of 13 amino acids and a constant region of 324 amino acids. After the stop codon at amino acid 447 there begins 96 bp of 3' untranslated sequences up to the polyA addition.

E.1.7 *Construction of a Direct Expression Vector for Mouse Mature Anti-CEA Kappa Chain*

Figure 6 illustrates the construction of the vector for mature mouse anti-CEA kappa chain.

First, an intermediate plasmid pHGH207-1, having a single trp promoter, was prepared as follows:

The 310 bp DNA fragment containing trp promoter was obtained from pF1Ftrp69, described in Goeddel et al., *Nucleic Acids Research* 8: 4057 (1980), incorporated herein by reference, by digestion with EcoRI and inserted into pHGH 107 (described in U.S. Pat. Application No.) incorporated herein by reference that had been opened with EcoR I, to obtain pHGH 207 which has a double lac promoter followed by the trp promoter, flanked by EcoR I sites. pHGH 207 was digested with Bamh I, followed by partial digestion with EcoRI and the largest fragment which contains the entire trp promoter was isolated. The largest EcoR 1-BamH I fragment was also isolated from pBR322. Both fragments were ligated and the mixture was used to transform *E. coli* 294. Tet^r, Amp^r colonies were isolated and most of them had the plasmid with the structure as shown for pHGH207-1.

Plasmid pHGH207-1 is thus a derivative of the plasmid pHGH107 and has the following properties: 1) the human growth hormone gene is flanked by the tryptophan promoter rather than the lac promoter, 2) the plasmid confers ampicillin and tetracycline resistance when expressed in *E. coli*. (See also European Patent Application Publication No. 0036776). A derivative of pHGH207-1 pHGH2076-1 was obtained, which lacks the EcoR I site between the amp^R gene and the trp promoter. This was accomplished by partial digestion of PHGE207-1 with EcoR I, filling in ends with Klenow and dNTPs, and religation to give pHGH207-1*.

5 µg of pHGH207-1* was digested with EcoRI, and the ends extended to blunt ends using 12 units of DNA Polymerase I in a 50 µl reaction containing 60 mM NaCl, 7 mM $MgCl_2$, 7 mM-Tris HCl (pH 7.4) and 1 mM in each dNTP at 37°C for 1 hour, followed by extraction with phenol/$CHCl_3$ and precipitation with ethanol. The precipitated DNA was digested with BamH I, and the large vector fragment purified

using 5 percent polyacrylamide gel electrophoresis, electroelution, phenol/$CHCl_3$ extraction and ethanol precipitation.

The DNA was resuspended in 50 µl of 10 mM Tris pH 8, 1mM EDTA and treated with 500 units Bacterial Alkaline Phosphatase (BAP) for 30' at 65° followed by phenol/$CHCl_3$ extraction and ethanol precipitation.

A partial gene insert was prepared as follows: 7 µg of pK1734 DNA was digested with Pst I and the kappa chain containing cDNA insert was isolated by 6 percent gel electrophoresis, and electoelution. After phenol/$CHCl_3$ extraction, ethanol precipitation and resuspension in water, this fragment was digested with Ava II. The 333 bp Pst I-Ava II DNA fragment was isolated and purified from a 6 percent polyacrylamide gel.

A 15 nucleotide DNA primer was synthesized by the phosphotriester method G. 0. 2,644,432 (supra) (G) and has the following sequence:

Met Asp Ile Val Met

5' ATG GAC ATT GTT ATG 3'

The 5' methionine serves as the initiation codon. 500 ng of this primer was phosphorylated at the 5' end with 10 units T4 DNA kinase in 20 µl reaction containing 0.5 nM ATP. -200 ng of the Pst I-Ava II DNA fragment was mixed with the 20 µl of the phosphorylated primer, heated to 95°C for 3 minutes and quick frozen in a dry-ice ethanol bath. The denatured DNA solution was made 60 mM NaCl, 7 mM $MgCl_2$, 7 mM Tris HCl (pH 7.4), 12 mM in each dNTP and 12 units DNA Polymerase I-Large Fragment was added. After 2 hours incubation at 37°C this primer repair reaction was phenol/$CHCl_3$ extracted, ethanol precipitated, and digested to completion with Sau 3A. The reaction mixture was then electrophoresed on a 6 Percent polyacrylamide gel and -50 ng of the 182 basepair amino-terminal blunt-end to Sau 3A fragment was electroeluted.

The blunt-Sau 3A primer-repair DNA fragment and ~100 ng of the BAP'd partial RI filled in, BamH I fragment from pHGH 207-1* were combined in 20 µl of 20 mM Tris HCl (pH 7.5), 10 mM $MgCl_2$, 10 mM DTT, 2.5 mM ATP and 1 unit of T4 DNA ligase. After overnight ligation at 14°C the reaction was transformed into *E. coli* K12 strain 294. Restriction endonuclease digestion of a number of ampicillin resistant transformants indicated the proper construction and DNA sequence analysis proved the desired nucleotide sequence through the initiation codon of this new plasmid, pKrepair1 (Figure 4).

The remainder coding sequence of the gene insert was prepared as follows:

> The Pst I cDNA insert fragment from 7 µg of K17G4 DNA was partially digested with Ava II and the Ava II cohesive ends were extended to blunt ends in a DNA Polymerase I large fragment reaction. Following 6 percent polyacrylamide gel electrophoresis the 686 basepair Pst I to blunt end Ava II DNA fragment was isolated, purified and subjected to Hpa II restriction endonuclease digestion. The 497 basepair Hpa II to blunt end Ava II DNA fragment was isolated and purified after gel electrophoresis.

10 µg of pKrepair1 DNA was digested with Ava I, extended with DNA polymerase I large fragment, and digested with Xba I. Both the large blunt end Ava I to Xba I vector fragment and the small blunt end Ava I to Xba I fragment were isolated and purified from a 6 percent polyacrylamide gel after electrophoresis. The large vector fragment was treated with Bacterial Alkaline Phoshatase, and the small fragment was digested with Hpa II, electrophoresed on a 6 percent polyacrylamide and the 169 basepair Xba I-Hpa II DNA fragment was purified (Figure E). ~75 ng of the BAP'd XbaI to blunt end Ava I vector DNA fragment, ~50 ng of the blunt ended partial Ava II to Hoa II DNA fragment and

50 ng of the Hpa II-Xba I overnight at 14°, and the reaction mixture transformed into *E. coli* K12 strain 294. Six ampicillin resistant transformants were selected for restrictions endonuclease analysis. One transformant demonstrated the proper construction and was designated pKcea trp 207-1.

E.1.8. *Construction of Direct Expression Vector for Mouse Mature Anti-CEA Gamma 1 Chain.*

Figure 7 illustrates the construction of the expression plasmid for mature mouse anti-CEA gamma 1 chain. This plasmid was constructed in two parts beginning with construction of the C-terminal region of gene. 5 μg of intermediate plasmid pHGH207-1 was digested with Ava I, extended to blunt ends with DNA polymerase I large fragment (Klenow fragment), extracted with phenol/$CHCl_3$, and ethanol precipitated. The DNA was digested with BamH I treated with BAP and the large precipitated fragment was recovered by 6 percent polyacrylamide gel electrophoresis and electroelution.

-5 μg of pγ1 was digested with Pst I and the gamma chain cDNA insert fragment containing the C-terminal portion of the gene was isolated and purified digested with Ava II followed by extension of the Ava II cohesive ends with Klenow and by Taq I digestion. The 375 basepair blunt end Ava II to Taq I fragment was isolated and purified by gel electrophoresis and electroelution.

9 μg of pγ298 was digested with Taq I and BamH I for isolation of the 496 basepair fragment.

Approximately equimolar amounts of the above described three fragments were ligated overnight at 14°, then transformed into *E. coli* strain 294. The DNA from six ampicillin resistant transformants was committed to restriction endonuclease analysis and one plasmid DNA, named pγceatrc, demonstrated the correct construction of the C-terminal potion of gamma 1 (Figure 5).

30 μg of pγ298 was digested with Pst I and the 628 basepair DNA fragment encoding the N-terminal variable region amino acid sequence of mouse anti-CEA gamma chain was isolated and purified. This fragment was further digested with Alu I and Rsa I For isolation of the 280 basepair fragment. A 15 nuclotide DNA primer

met glu val met leu

5' ATG GAA GTG ATG CTG 3'

was synthesized by the phosphotriester method (supra).

The 5' methionine serves as the initiation codon. 500 ng of this synthetic oligomer primer was phosphorylated at the 5' end in a reaction with 10 units T4 DNA kinase containing 0.5 mM ATP.-500 ng of the 280 basepair Ala I Rsa I DNA fragment was mixed with the phosphorylated primer. The mixture was heat denatured for 5 minutes at 95° and quench frozen in dry-ice ethanol. The denatured DNA solution was treated in a manner identical to the kappa chain region reaction except that after 37° incubation and clean up of the reaction the DNA was digested with Hpa II before gel electrophoresis. -50 ng of the expected 125 basepair blunt-end to Hpa II DNA fragment was purified from the gel.

A second aliquot of pγ298 DNA was digested with Pst I and the 628 basepair DNA fragment was isolated from a polyacrylamide gel for further digestion with BamH I and Hpa II. The 380 basepair fragment was isolated and purified from this digest.

-5 μg of pγcearec was digested with EcoR I and the cohesive ends were made flush with Klenow, further digested with BamH I, BAP'd and electrophoresed on a 6 percent polyacrylamide gel. The large vector fragment was isolated and purified.

In a three fragment ligation, the 125 bp blunt-end to Hpa II fragment was combined with -100 ng of the 380 bp BamH I

Hoa II and -100 ng of the BAP'd pγceatro fragment, and ligated overnignt at 4°. *E. coli* K12 strain 294 was transformed with the ligase reaction. The plasmid DNA from 12 ampicillin resistant transformants was analyzed for the correct construction and the nucleotide sequence through the initiation codon was verified for one plasmid DNA, named pγceatrp 207-1.

E.1.9 *Production of Gamma Chain by Cells transformed with Pγceatrp 207-1.*

E.1.10 *Production of Kappa Chain by Cells Transformed with pKceatrp 207-1.*

E.1.11 *Reconstitution of Antibody from Recombinant K and Gamma Chains*

E.2 *Assay Method*

E.3 *Preparation of Hybrid Antibody*

E.4 *Preparation of Fab*

E.4.1 *Construction of Mouse Anti-CEA Gamma 1 Fab Fragment Vector*

Figure 3 presents the construction of an expression vector for mouse anti-CEA gamma 1 Fab fragment. 5 μg of pBR322 was digested with Hind III, the cohesive ends made flush by filling in using Klenow enzyme; digested with Pst I, BAP'd and electrophoresed through a 6 percent polyacrylamide gel. The large vector fragment was isolated and purified from the gel.

5 μg of pγceatrp207-1* was digested with both BamH I and Pst I and the -1570 bp DNA fragment containing the trp promoter and the gene sequence encoding the variable region continuing into constant region and further into the anti-CEA gamma 1 chain hinge region, was isolated and purified after electrophoresis.

Expression of the anti-CEA gamma 1 chain Fab fragment requires that a termination codon be constructed at the C-terminus of the gene. For this, the 260 bp Nce I to Nde I DNA fragment from 20 μg of the pγ298 was isolated and purified. A 13 nucleotide DNA primer, the complement of which encodes the last 3 C-terminal amino acids of the Fab gene and 2 bases of the 3 needed for the stop codon, synthesized by the phosphotriester method (supra) and has the following sequence:

AspCysGlyStop

3' CCCTAAACACCAAC 5'

The third base of the stop codon is provided by the terminal nucleotide of the filled-in Hind III site op cit. 500 ng of this primer was used in a primer repair reaction with -200 ng of the Nco I Nde I DNA fragment. The DNA was then digested with BamH I and the reaction electrophoresed through a 6 percent polyacrylamide gel. -50 ng of the 181 bp blunt end to BamH I DNA fragment was isolated and purified.

-100 ng of the BAP'd filled-in Hind III-Pst I vector fragment, -100 ng of the BamH I Pst I fragment and the 181 basepair blunt end to BamH I repair fragment was ligated overnight and transformed into *E. coli* K12 strain 294. Plasmid DNA from several tetracycline resistant transformants was analyzed for the proper construction and the nucleotide sequence through the repair blunt end filled-in Hind III junction was determined for verification of the 5' TGA stop codon.

E.4.2 *Expression of Gene for Gamma Fab Fragment*

Claims

1. Antibodies produced by recombinant host cells.
2. Antibodies substantially free of other proteins of mammalian origin.

3. The antibodies of Claim 1 or 2 which are mammalian antibodies in that the amino acid sequences of all four chains are homologous to the sequences in the corresponding chains in antibodies derived from a mammalian species.

4. The antibodies of Claim 3 wherein the mammalian species is murine.

5. The antibodies of Claim 3 wherein the mammalian species is human.

6. The antibodies of Claim 1 or 2 which are composite antibodies.

7. The antibodies of Claim 6 which are divalent antibodies.

8. The antibodies of Claim 6 wherein the amino acid sequences of one pair of heavy and light chain is homologous to the corresponding amino acid sequences of the antibodies raised in response to a first antigen species, and the amino acid sequences of the other pair of heavy and light chain is homologous to the corresponding amino acid sequences of antibodies raised in response to a second, different, antigen.

9. The antibodies of Claim 6 or 7 wherein the homology of the heavy chains corresponds to murine antibodies, and the homology of the light chains corresponds to human antibodies.

10. The antibodies of Claim 1 or 2 which are hybrid antibodies.

11. The antibodies of Claim 10 wherein the constant regions of all four chains are homologous to the corresponding constant regions of antibodies of a first mammalian species, and the amino acid sequence of the variable regions of all four chains are homologous to the variable regions in antibodies derived from a second, different, mammalian species.

12. The antibodies of Claim 11 wherein the homology of the constant regions corresponds to murine antibodies and the homology of the variable region corresponds to human antibodies.

13. The antibodies of Claims 1, 2, 3, 6, or 10 which are antigenic against CEA.

14. The antibodies of Claims 1, 2, 3, 6, or 10 wherein the heavy chain is of the gamma family.

15. The antibodies of Claims 1, 2, 3, 6, or 10 wherein the light chain is of the kappa family.

16. A composition of matter consisting essentially of Fab region.

17. The composition of matter of Claim 16 which is produced by recombinant host cells.

18. The composition of matter of Claim 17 which is Mammalian Fab region.

19. The composition of matter of Claim 17 which is a divalent Fab region.

20. The composition of matter of Claim 17 which is a hybrid Fab region.

21. The composition of matter of Claim 20 wherein the amino acid sequence of the variable region wherein the amino acid sequences of the variable region of both chains is homologous to corresponding sequences of antibodies derived from a first mammalian species, and the amino acid sequences of the constant regions of both chains are homologous to the corresponding amino acid sequences of antibodies derived a second, different mammalian species.

22. The composition of matter of claims 16 through 20 wherein the composition of matter is immunoreactive against CEA.

23. A sequence of amino acids produced by recombinant host cells corresponding to the heavy chain of antibody.

24. The sequence of Claim 23 which is a mammalian heavy chain.

25. The sequence of Claim 24 which is homologous to the heavy chain of a human or murine antibody.

26. The sequence of Claim 23 which is a hybrid heavy chain.

27. The sequence of Claim 26 wherein that portion of the sequence which corresponds to the variable region is homologous to corresponding sequences of antibodies derived from a first mammalian species, and the amino acid sequences of the constant regions of both chains are homologous to the corresponding amino acid sequences of antibodies derived a second, different mammalian species.

28. The sequence of Claim 23 through 27 which corresponds to the sequences of the gamma family.

29. A sequence of amino acids produced by recombinant host cells corresponding to the light chain of a mammalian antibody.

30. The sequence of Claim 29 which is a mammalian light chain.

31. The sequence of Claim 30 which is homologous to the light chain of a murine or human antibody.

32. The sequence of Claim 29 which is a hybrid light chain.

33. The sequence of Claim 32 wherein that portion of the sequence which corresponds to the variable region is homologous to corresponding sequences of antibodies derived from a first mammalian species, and the

amino acid sequences of the constant regions of both chains are homologous to the corresponding amino acid sequences of antibodies derived a second, different mammalian species.

34. The amino acid sequence of Claims 29 through 33 which corresponds to the sequence of the kappa family.

35. A DNA sequence which codes for the antibody of Claims 1, 2, 3, 6, or 10.

36. A replicable expression vector capable of expressing in a suitable host cell the DNA sequence of Claim 35.

37. An expression plasmid which comprises the DNA sequence of Claim 35 operably linked to a promoter compatible with a suitable host cell.

38. A DNA sequence which encodes for the composition of matter of Claim 16 or 17.

39. A replicable expression vector capable of expressing in a suitable host cell the DNA sequence of Claim 38.

40. An expression plasmid which comprises the DNA sequence of Claim 38 operably linked to a promoter compatible with a suitable host cell.

41. A DNA sequence which codes for the amino acid sequence of Claim 23.

42. A replicable expression vector capable of expressing in a suitable host cell the DNA sequence of Claim 41.

43. An expression plasmid which comprises the DNA sequence of Claim 41 operably linked to a promoter compatible with a suitable host cell.

44. A DNA sequence which encodes the amino acid sequence of Claim 29.

45. A replicable expression vector capable of expressing in a suitable host cell the DNA sequence of Claim 44.

46. An expression plasmid which comprises the DNA sequence of Claim 44 operably linked to a promoter compatible with a suitable host cell.

47. Recombinant host cells or host cell cultures transformed with the vector of Claim 36 or 37.

48. Recombinant host cells or host cell cultures transformed with the vector of Claim 39 or 40.

49. Recombinant host cells or host cell cultures transformed with the vector of Claim 42 or 43.

50. Recombinant host cells or host cell cultures transformed with the vector of Claim 45 or 46.

51. A method for reconstituting antibody heavy and light chains, which method comprises treating an approximately equimolar mixture of such chains with a mild denaturant in the presence of a reducing agent, followed by dialysis into dilute buffer in the presence of air.

52. The method of Claim 51 wherein heavy and light chains are derived from recombinant host cell culture.

53. A method for preparing antibodies in recombinant host cells which method comprises

    a) preparing a DNA sequence encoding heavy chain,

    b) inserting the sequence of a) into a replicable expression vector operably linked to a suitable promoter,

    c) preparing a DNA sequence encoding light chain,

    d) inserting the sequence of c) into a replicable expression vector operably linked to a suitable promoter,

    e) transforming host cell culture with the vector of b) and host cell culture with the vector of d),

f) recovering light chain and heavy chain from cell culture,

g) reconstituting light and heavy chain.

54. The method of Claim 53 wherein the vector of b) and the vector of d) are used to transform the same host cell culture.

55. The method of Claim 54 wherein the sequence of a) and the sequence of a) are inserted into the same replicable expression vector.

56. The method of Clam 53 wherein the DNA sequence of a) encodes mammalian heavy chain, and the DNA sequence of c) encodes mammalian light chain; and wherein both DNA fragments encode amino acid sequences of the same mammalian antibody.

57. The method of Claim 53 wherein the DNA sequence in a) encodes a mammalian heavy chain, the DNA sequence in b) encodes mammalian light chain, and wherein the DNA fragments of light and heavy chain encode for amino acid sequences which correspond to sequences from different mammalian antibodies.

58. The method of Claim 53 wherein the DNA fragment of a) encodes hybrid heavy chain and the DNA sequence of c) encodes hybrid light chain.

59. A method for preparing Fab region in recombinant host cells which method comprises

a) preparing a DNA sequence encoding the Fab region of heavy chain

b) inserting the sequence of a) into a replicable expression vector operably linked to a suitable promoter,

c) preparing a DNA sequence encoding light chain.

d) inserting the sequence of b) into a replicable expression vector operably linked to a suitable promoter,

e) transforming host cell culture with the vector of B and host cell culture with the vector of D,

f) recovering light chain and Fab region of heavy chain from cell culture,

g) reconstituting light and heavy Fab region chains.

60. The method of Claim 59 wherein the DNA sequence in a) encodes a mammalian heavy chain Fab region and the DNA sequence in c) encodes a mammalian light chain.

61. The method of Claim 59 wherein the DNA sequence in a) encodes a mammalian Fab region of heavy chain corresponding to Fab of one mammalian antibody, and the DNA sequence in c) encodes for light chain of another mammalian antibody.

62. The method of Claim 59 wherein the DNA sequence in a) encodes hybrid Fab region of a heavy chain, and the DNA sequence in c) encodes a hybrid light chain.

63. A method for preparing antibody heavy chain which method comprises preparing

a) a DNA sequence encoding heavy chain,

b) inserting said sequence into a replicable expression vector operably linked to a suitable promoter,

c) transforming host cell culture with the vector of b) and

d) recovering heavy chain from cell culture.

64. A method for preparing antibody light chain which method comprises preparing

a) a DNA sequence encoding light chain,

b) inserting said sequence into a replicable expression vector operably linked to a suitable promoter,

c) transforming host cell culture with the vector of b),

d) recovering light chain from cell culture.

65. A method for preparing antibody Fab region which method comprises preparing

a) a DNA sequence encoding Fab region,

b) inserting said sequence into a replicable expression vector operably linked to a suitable promoter,

c) transforming host cell culture with the vector of b),

d) recovering Fab region from cell culture.

[*Exhibit 3 to Winters Declaration*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

No. C98-3926 MMC ENE

GENENTECH, INC.

Plaintiff,

vs.

CELLTECH THERAPEUTICS, LTD.,

Defendant.

DEPOSITION UPON ORAL EXAMINATION OF
DOCTOR SHMUEL CABILLY

Volume II
(Pages 165-322)

On Wednesday, 2nd February 2000
Commencing at 9:15 a.m.

Taken at the offices of
Morrison & Foerster
21 Garlick Hill
London EC4, England.

Reported by Alan J. Bell, MBIVR, MNCRA

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* * *

[275] A. It is a fact that I prepared them from them. I do not remember, apart from this case, that I gave other people cotransformed cells, right now.

Q. Other than this instance where you gave samples to Jeanne Perry, do you remember any other instance where you gave samples derived from cotransformed cells?

MR. WINTERS: Same objection.

THE WITNESS: I cannot remember, no.

BY MR. KREEGER:

Q. Do you have any financial interest in royalties or otherwise associated with if Genentech prevails and gets a patent in this case?

A. Not that I know right now.

MR. WINTERS: I am sorry, objection: vague; may call for a legal conclusion. You can answer.

THE WITNESS: Not that I know right now.

(Exhibit 101 was marked for identification)

BY MR. KREEGER:

Q. I am showing you what has been marked as Exhibit 101 and I ask if you recognize [276] this document.

A. Yes.

Q. At one point in your deposition you mentioned having found a draft of the patent application. Is this the patent application that was recently found?

MR. WINTERS: It is vague, but—

MR. KREEGER: I am sorry, I did not mean to interrupt you.

A. I think that a copy of this one I saw before. Now, this copy was in my possession, OK.

Q. This was in your possession, Exhibit 101?

A. Yes.

Q. There was another draft that was in your possession. Is that right?

A. Yes.

(Exhibits 102 and 103 were marked for identification)

MR. WINTERS: I am sorry, I am going to object, because you are calling two moves that have busted me. Apparently there is a local rule [277] about not marking as exhibits parts of the same document. 102, and I think what you have marked as 103, were produced together.

MR. KREEGER: OK. In the version that we were produced, they were not literally affixed to one another. I was just about to ask him if they were part of the same document.

MR. WINTERS: Fine.

BY MR. KREEGER:

Q. When you found these in your files, was the cover letter attached to the draft that is sitting next to it?

A. Can I see it first?

Q. You may.

A. Because this is a different—

Q. Please.

MR. FITTON: They were not attached.

MR. WINTERS: By "attached" do you mean affixed or attached do you mean a part of?

BY MR. KREEGER:

Q. I mean attached to one another, affixed.

A. In my folder they were one above the other one.

[278] Q. Just so the record is clear, the one-page document that I have marked as Exhibit 103 was sitting on top of the document that we have marked as Exhibit 102?

A. Yes.

Q. Sitting here today, do you know if you received Exhibit 103 and Exhibit 102 together?

A. I assume I received them, I think that I received them, together.

Q. There is some marking on Exhibit 102?

A. OK.

Q. Are those your marks?

MR. WINTERS: Would you like the original?

THE WITNESS: I would prefer to look at the original.

MR. KREEGER: The witness is now looking at the original of the same document.

A. Some of them; some of them, yes.

Q. Some of the marking is not yours?

A. Some of them are not.

Q. The marks that were not yours; were they present when you received the draft patent [279] application?

MR. WINTERS: Do you understand the question?

A. Yes, I understand. No. No, to the best of my ability to judge, they came clean.

BY MR. KREEGER:

Q. Can you tell whose marking is on there other than yours?

A. It seems Art's, Art Riggs.

Q. Could you indicate which are the pages that have Dr. Riggs' writing on them?

A. Yes.

MR. WINTERS: By that it may be that both Dr. Riggs and Dr. Cabilly wrote on them, but you want those pages in which some or all of the handwriting is Dr. Riggs'?

MR. KREEGER: Right.

A. The first page contains Dr. Riggs.

Q. He wrote the "revertebrate"?

A. Yes, and the upper part. Page number 2 also, some of them are of Dr. Riggs.

Q. Which of those are Dr. Riggs?

A. You can tell by the handwriting, line 3 it is Dr. Riggs. Then in the middle of the [280] first paragraph, we have "the resulting genome" and above it you will see Dr. Riggs' handwriting.

MR. WINTERS: Is there a way to tell, pen or pencil? Can I just suggest that question is a way to differentiate between his and Riggs.

BY MR. KREEGER:

Q. My photocopy does not make that clear. Can you tell?

A. No, because this is pencil and this is my handwriting.

MR. WINTERS: OK, I did not know. I just thought it might make it quicker.

BY MR. KREEGER:

Q. Is it mostly Riggs?

A. No, you see some of the references there are mine.

Q. The parentheses and the numbers?

A. Yes, they are mine. This, on page 3, you have "myeloma" and the references are mine. Page 4 is my handwriting. Page 5, this is my handwriting at the middle of it. Then, further on, page 9 is Art Riggs' handwriting. Page 22, that is my handwriting. Page 33 it is not my [281] handwriting. Page 35, at the bottom, it is Art Riggs' handwriting. And that is it.

Q. Do you know when it was that you received the draft patent application, Exhibit 102?

A. In terms of what, years, month, days, hours?

Q. I think you will see the cover letter is dated February 25th 1983 and I was wondering if you knew when it was that you actually received it?

A. Right now, I cannot tell you.

Q. What about the draft that is marked as Exhibit 101. Do you know when you received that draft? First of all, I take it that Exhibit 101 also came from your files, or is that not true?

A. Yes, it came from my files. This is 101?

Q. 101, yes. Why do you not look at the exhibit here.

A. OK.

Q. This one also came from your files?

A. Yes.

Q. You received Exhibit 101 after you received Exhibit 102?

[320] A. I did not ask; I do not know.

MR. WINTERS: So the record is clear, I think the answer to that is "Yes".

My understanding is yes, that Genentech thinks it is appropriate—given Dr. Cabilly's extremely impacted schedule and where he is in his life—to compensate him for his time and they are doing it.

THE WITNESS: Now I thank you!

MR. KREEGER: I am through. Thank you very much.

(The deposition concluded at 2.42 p.m.)

[*Exhibit 12 to Winters Declaration*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

No. C-98-3926

GENENTECH, INC.

Plaintiff,

vs.

CELLTECH LIMITED,

Defendant.

REPORTER'S TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE MAXINE M. CHESNEY
UNITED STATES DISTRICT JUDGE
JULY 28, 2000

APPEARANCES:

FOR THE PLAINTIFF: GENENTECH INCORPORATED
LATHAM & WATKINS
BY: VERNON WINTERS, Esq.
135 Commonwealth Drive
Menlo Park, CA 94025

[2] LATHAM & WATKINS
BY: WILL B. FITTON, Esq.
505 Montgomery St. #1900
San Francisco, CA 94111

FOR THE DEFENDANT: CELLTECH LIMITED
MORRISON & FOERSTER
BY: MATTHEW KREEGER, Esq.
BY: TAMU K. SUDDUTH, Esq.
425 Market Street
San Francisco, CA 94105

* * *

[91] MR. KREEGER: And the Court may have questions as well.

MR. WINTERS: Of course.

THE COURT: I may well. Also I think that there are ways that you can narrow some of the testimony certainly with respect to the qualifications of the witnesses. You can maybe highlight a couple of noble [*sic*] prizes or something and go on, you know.

You don't have to give me every paper they wrote and then every school they attended and just maybe highlight a couple of things that are particularly impressive.

All of these people respect each other and that suggest [*sic*] that they're all qualified and impressive people in their own right.

I would like to take up a housekeeping matter as well. We talked at the last calling of the case which was a case management conference about whether there was any possibility the case resolving by way of agreement as opposed to full [92] litigation of which it's going to be long, expensive and won't even be the end, as I understand it, this can go up after I rule, correct?

MR. WINTERS: Yes.

MR. KREEGER: Yes.

THE COURT: So you know I don't want to just characterize myself as a waste [*sic*] station but given the fact that your clients have so much apparently at steak [*sic*] and so con-

cerned about the matter, I'd be hard pressed to see whoever does not prevail, doesn't want to go further with the matter.

So that if you're really trying to resolve it and have some type of a completion of this matter within some reasonable period of time, and I guess more than a reasonable amount has already gone on, but from this point I was encouraging you to, at least, see about the potential ADR. And you told me I believe that the choice would be private mediation.

MR. WINTERS: Yeah.

MR. KREEGER: Yes.

THE COURT: Have you set something up?

MR. WINTERS: We haven't. We've [93] discussed with a retired Judge Lynch. Genentech had used before and been happy with that performance.

We're willing to take that to mediation, set a date for that.

THE COURT: You have?

MR. WINTERS: Yeah. We haven't set that up. The Court set a date. Looks like we may have a mediator preference between the parties so I expect early next week we'll try to get that going.

THE COURT: I would hope you would agree on a mediator. Judge Lynch, as you know, was a member of this bench and conducted a reduced-rate settlement conference to witness mediations here on the bench, but he has left the bench.

MR. .WINTERS: Increased his rate.

MR. KREEGER: I have no doubt we'll find an agreement.

THE COURT: You need to get going on that.

MR. WINTERS: Very well.

THE COURT: Because this is not something that you can just pop in for a couple of minutes and then it's all over.

I think if you're going to admit [94] yourself to actually engaging in the process, you really have to put your full effort into it. So the sooner you get that scheduled the better.

* * *

[*Exhibit 15 to Winters Declaration*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

CASE NO. C98-3926 MMC (WDB)

GENENTECH, INC.,

Plaintiff,

v.

CELLTECH THERAPEUTICS, LTD.,

Defendant.

NOTICE OF SETTLEMENT AND JOINT REQUEST FOR ENTRY OF SETTLEMENT INSTRUMENTS

This Notice Relates to a Status Conference Scheduled for March 9, 2001 at 10:30 A.M.

The Parties have reached a settlement of this matter and all settlements documents have been duly executed. As part of the settlement, the Parties have agreed that an Order and Judgment should issue from this Court, the effect of which will be to order the Patent and Trademark Office (PTO) to (i) vacate the decision in *Cabilly, et al. v. Boss et al.*, Patent Interference No. 102,572, (ii) revoke and vacate United States Patent No. 4,816,397, issued March 28, 1989 (the Celltech Patent), and (iii) grant and issue a United States patent based upon pending United States Patent Application No. 07/215,419, such patent having those claims 101-120 that were allowed by the PTO in such pending patent application (the Genentech Patent). The Parties' settlement is conditioned upon the Court issuing the Order and the Judgment and upon the PTO taking the prescribed actions.

The proposed Judgment and Order (two separate documents) are being filed herewith. The Judgment is the

document which directs the PTO to take certain actions and retains jurisdiction to ensure such actions are taken. The Order contains findings of fact related to the judgment, vacates certain prior orders, and provides for the return of documents filed under seal. The Parties jointly request the Court to enter both the Judgment and the Order.

While the Parties believe the Judgment and Order are self-explanatory, the stand ready to provide, through whatever means the Court desires, additional explanation or argument in support of the entry of such instruments. As discussed at the February 16, 2001, telephonic status conference, the Parties stand ready to attend the March 9, 2001, telephonic status conference unless they are advised by the courtroom deputy that their attendance is not necessary.

Dated: March 6, 2001

Respectfully submitted,

LATHAM & WATKINS

By /s/ Daniel Wall by Rachel Krevans by permission
DANIEL M. WALL
Attorneys for GENENTECH, INC.

Dated: March 6, 2001

Respectfully submitted,

MORRISON & FOERSTER

By /s/ Rachel Krevans
RACHEL KREVANS
Attorneys for CELLTECH
THERAPEUTICS, LTD.

[*Exhibit 16 to Winters Declaration*]

[Proposed Order]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

CASE NO. C98-3926 MMC

GENENTECH, INC.,

Plaintiff,

v.

CELLTECH THERAPEUTICS, LTD.,

Defendant.

[Proposed] Order Regarding Resolution of Interference

The Court hereby makes the following orders in this case:

[Proposed] Findings of fact and conclusions of law

1. Plaintiff, Genentech, Inc. filed this action under 35 U.S.C. § 146, following a decision in Patent Interference No. 102,572 before the Board of Patent Appeals and Interferences ("Board") of the United States Patent and Trademark Office ("PTO"). In that decision the Board concluded that Michael A. Boss, John H. Kenten, John S. Emtage and Clive R. Wood (collectively "Celltech Inventors") were entitled to priority over Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur .D. Riggs, and Ronald B. Wetzel (collectively "Genentech's inventors") with respect to the invention defined by the interference count, which corresponded to claims 1-18 of U.S. Patent No. 4,816,397 ("the Boss patent"), issued to Celltech's inventors and assigned to Celltech.

2. The invention at issue relates to a process for producing genetically engineered immunologically functional antibodies, also referred to as immunoglobulin ("Ig") molecules. Immunologically functional Ig molecules (i.e., Ig molecules capable of binding with their associated antigen at levels above background) have a variety of potential uses including use as reagents in laboratory procedures and as therapeutic agents.

3. In the early 1980s, both Genentech and Celltech studied the use of recombinant DNA technology to produce Ig molecules. At roughly the same time, both developed the means to create immunologically functional Ig molecules. The dispute in this case is who first satisfied the requirements of the United States patent laws with regards to conception, and thus who had priority to the patent. In particular, the dispute centers on who first "conceived" the means to produce immunologically functional Ig molecules. The patent laws define "conception" as the purely mental act occurring when the inventor forms a definite and permanent idea of the complete and operative invention, such that one of ordinary skill could reduce the invention to practice without extensive research or experimentation. The date of conception must be corroborated by evidence other than the inventor's testimony, such as laboratory notebooks, patent applications or drafts, or other documentary evidence.

4. Celltech claims a priority date of March 25, 1983, the date it filed a British patent application describing the invention, and therefore proving conception. Accordingly, in order for Genentech to establish priority, it must prove and corroborate a conception prior to March 25, 1983.

5. Genentech filed its U.S. patent application on April 8. 1983 and Celltech filed its U.S. patent application in November 14, 1984. On March 28, 1989, part of Genentech's application issued as U.S. Patent No. 4,816,517, "Recombinant Immunoglobulin Preparations," and Celltech's application also issued as U.S. Patent No. 4,816,397, "Multichain Polypeptides or Proteins and Processes for their Production." Thereafter, Genentech amended a pending continuation of its application to copy exactly the claim in Celltech's patent, the permitted and standard procedure for provoking an interference.

6. On February 28, 1991, the PTO's Board of Patent Appeals and Interferences declared an interference between Celltech's patent and Genentech's continuation application. Genentech was originally named the senior party to the interference on account of its earlier U.S. filing date. However, Celltech thereafter filed a motion to be named the senior party, arguing that its priority British patent application corroborated a complete conception of the invention before Genentech first filed its U.S. patent application. That motion was granted, and ultimately the PTO concluded that because Genentech failed to prove a conception earlier than March 28, 1983, Celltech was entitled to priority.

7. Genentech commenced this action on October 9, 1998. Discovery ensued and was completed. During the course of discovery, additional evidence of Genentech research on immunologically functional Ig molecules was uncovered, including a draft of what became Genentech's U.S. patent application, which draft is dated February 25, 1983—a month before Celltech failed its British patent application. The PTO did not consider this draft patent application.

8. It is undisputed that if this draft is sufficient to corroborate conception of the invention as of February 25, 1983, Genentech is entitled to priority. Celltech does not claim any basis for an earlier priority date.

9. Genentech's February 25, 1983 draft patent application is sufficient to corroborate Genentech's complete conception of the invention by that date. The description of the invention contained in the draft shows that Genentech's inventors had formed, by February 25, 1983, a definite and permanent idea of the complete and operative invention, such that one of ordinary skill could reduce the invention to practice without extensive research or experimentation. Furthermore, the description of the invention contained in Genentech's draft is at least equivalent to the description contained in Celltech's British application, upon which the PTO relied in concluding that Celltech was entitled to priority

10. Accordingly, the Court finds and rules that Genentech is entitled as a matter of law to priority over Celltech to the invention described by the count.

Vacating of prior Orders

The Court hereby vacates the following prior Orders in this case:

1. The Orders of Magistrate Judge Wayne D. Brazil dated January 14, 2000.

2. This Court's Order dated February 17, 2000 denying Genentech's appeal of Magistrate Judge Brazil's January 14, 2000 Order.

3. This Court's Order dated July 31, 2000 denying plaintiff Genentech Inc.'s summary adjudication and count construction motions.

Documents filed under seal

1. In addition, the Court hereby directs the Clerk of the Court to allow counsel for the parties to remove from the court's files all documents filed under seal in this case. As those documents were filed under seal, they did not become part of the public record in this case.

IT IS SO ORDERED.

Dated: March __, 2001.

By_____
United States District Judge

[*Exhibit 17 to Winters Declaration*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

CASE NO. C98-3926 MMC

GENENTECH, INC.,

Plaintiff,

v.

CELLTECH THERAPEUTICS, LTD.,

Defendant.

[Proposed] Judgment

Plaintiff, Genentech, Inc., filed this action under 35 U.S.C. § 146 following a decision in Patent Interference No. 102,572 before the Board of Patent Appeals and Interferences ("Board") of the United States Patent and Trademark Office ("PTO"). In that decision, the Board concluded that Michael A. Boss, John H. Kenten, John S. Emtage, and Clive R. Wood (collectively "Celltech's inventors") were entitled to priority over Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel (collectively "Genentech's inventors") with respect to the invention defined by the interference count, which corresponded to claims 1-18 of issued US Patent No. 4,816,397.

Pursuant to Rule 54(b) of the Federal Rules of Civil Procedure, the Court orders and adjudges that the following shall occur simultaneously:

1. The Court directs the PTO to vacate the PTO's decision in *Cabilly, et al v. Boss, et al.*, Patent Interference No. 102, 572.

2. The Court directs the PTO to revoke and vacate United States Patent No. 4,816,397, issued March 28, 1989 to Boss, *et al.*;

3. The Court directs the PTO to grant and issue to Genentech's Inventors with Genentech as the assignee), with the issue date being the same as the date of revocation of United States Patent No. 4,816,397, a United States patent having those claims 101-120 that were allowed by the PTO in Genentech's pending United States Patent Application No. 07/205,419, which is a continuation of Genentech's United States Application No. 06/483,457, filed April 8, 1983.

The Court shall retain jurisdiction over this matter pending the PTO's compliance with the above orders and this Judgment. If for any reason the PTO does not comply with the orders set out above, then these orders, this Judgment, and the Order regarding resolution of the interference shall be vacated, and shall have no force and effect, and shall not be relied upon by any person for any purpose, and Genentech and Celltech shall promptly proceed to arbitration as provided in the Settlement Negotiation and Alternative Dispute Resolution Agreement between Genentech and Celltech dated September 18, 2000.

The parties shall bear their own respective attorneys' fees and costs.

IT IS SO ADJUDGED.

Dated: March __, 2001.

By _____
United States District Judge

[*Exhibit 18 to Winters Declaration*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

[Filed March 16, 2001]

Case No. C98-3926 MMC (WDB)

GENENTECH, INC.,

Plaintiff,

vs.

CELLTECH THERAPEUTICS, LTD.,

Defendant.

Order Regarding Resolution of Interference

Pursuant to the settlement agreement between the parties, the Court hereby makes the following orders in this case:

Findings of fact and conclusions of law

1. Plaintiff, Genentech, Inc., filed this action under 35 U.S.C. § 146, following a decision in Patent Interference No. 102,572 before the Board of Patent Appeals and Interferences ("Board") of the United States Patent and Trademark Office ("PTO"). In that decision, the Board concluded that Michael A. Boss, John H. Kenten, John S. Emtage, and Clive R. Wood (collectively "Celltech's inventors") were entitled to priority over Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel (collectively "Genentech's inventors") with respect to the invention defined by the interference count, which corresponded to claims 1-18 of U.S. Patent No. 4,816,397 ("the Boss patent"), issued to Celltech's inventors and assigned to Celltech.

2. The invention at issue relates to a process for producing genetically engineered immunologically functional antibodies, also referred to as immunoglobulin ("Ig") molecules immunologically functional Ig molecules (i.e., Ig molecules capable of binding with their associated antigen at levels above background) have a variety of potential uses, including use as reagents in laboratory procedures and as therapeutic agents.

3. In the early 1980's, both Genentech and Celltech studied the use of recombinant DNA technology to produce Ig molecules. At roughly the same time, both developed the means to create immunologically functional Ig molecules. The dispute in this case is who first satisfied the requirements of the United States patent laws with regards to conception, and thus who had priority to the patent. In particular, the dispute centers on who first "conceived" the means to produce immunologically functional Ig molecules. The patent laws define "conception" as the purely mental act occurring when the inventor forms a definite and permanent idea of the complete and operative invention, such that one of ordinary skill could reduce the invention to practice without extensive research or experimentation. The date of conception must be corroborated by evidence other than the inventor's testimony, such as laboratory notebooks, patent applications or drafts, or other documentary evidence.

4. Celltech claims a priority date of March 25, 1983, the date it filed a British patent application describing the invention, and therefore proving conception. Accordingly, in order for Genentech to establish a priority, it must prove and corroborate a conception prior to March 25, 1983.

5. Genentech filed its U.S. patent application on April 8, 1983 and Celltech filed its U.S. patent application in November 14, 1984. On March 28, 1989, part of Genentech's application issue as U.S. Patent No. 4,816,517, "Recombinant immunoglobulin Preparations," and Celltech's application

also issued as U.S. Patent No. 4,816,397, "Multichain Polypeptides or Proteins and Processes for their Production." Thereafter, Genentech amended a pending continuation of its application to copy exactly the claim in Celltech's patent, the permitted and standard procedure for provoking an interference.

6. On February 28, 1991, the PTO's Board of Patent Appeals and Interferences declared an interference between Celltech's patent and Genentech's continuation application. Genentech was originally named the senior party to the interference, on account of its earlier U.S. filing date. However, Celltech thereafter filed a motion to be named the senior party, arguing that its priority British patent application corroborated a complete conception of the invention before Genentech first filed its U.S. patent application. That motion was granted, and ultimately the PTO concluded that because Genentech failed to prove a conception earlier than March 28, 1983, Celltech was entitled to priority.

7. Genentech commenced this action on October 9, 1998. Discovery ensued and was completed. During the course of discovery, additional evidence of Genentech's research on immunologically functional Ig molecules was uncovered, including a draft of what became Genentech's U.S. patent application, which draft is dated February 25, 1983—a month before Celltech filed its British patent application. The PTO did not consider this draft patent application.

8. It is undisputed that if this draft is sufficient to corroborate conception of the invention as of February 25, 1983, Genentech is entitled to priority. Celltech does not claim any basis for an earlier priority date.

9. Genentech's February 25, 1983 draft patent application is sufficient to corroborate Genentech's complete conception of the invention by that date. The description of the invention contained in the draft shows that Genentech's inventors had formed, by February 25, 1983, a definite and

permanent idea of the complete and operative invention, such that one of ordinary skill could reduce the invention to practice without extensive research or experimentation. Furthermore, the description of the invention contained in Genentech's draft is at least equivalent to the description contained in Celltech's British application, upon which the PTO relied in concluding that Celltech was entitled to priority.

10. Accordingly, the Court finds and rules that Genentech is entitled as a matter of law to priority over Celltech to the invention described by the count.

Vacating of prior Orders

The Court hereby vacates the following prior Orders in this case:

1. The Order of Magistrate Judge Wayne D. Brazil dated January 14, 2000.

2. This Court's Order dated February 17, 2000 denying Genentech's appeal of Magistrate Judge Brazil's January 14, 2000 Order.

3. This Court's Order dated July 31, 2000 denying plaintiff Genentech, Inc.'s summary adjudication and count construction motions.

Documents filed under seal

1. In addition, the Court hereby directs the Clerk of the Court to allow counsel for the parties to remove from the courts files all documents filed under seal in this case. As those documents were filed under seal, they did not become part of the public record in this case.

IT IS SO ORDERED

Dated: March 16, 2001

By: /s/ Maxine M. Chesney
United States District Judge

[*Exhibit 19 to Winters Declaration*]

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

[Filed March 16, 2001]

Case No. C98-3926 MMC (WDB)

GENENTECH, INC.,

Plaintiff,

vs.

CELLTECH THERAPEUTICS, LTD.,

Defendant.

Judgment

1. Plaintiff, Genentech, Inc., filed this action under 35 U.S.C. § 146, following a decision in Patent Interference No. 102,572 before the Board of Patent Appeals and Interferences ("Board") of the United States Patent and Trademark Office ("PTO"). In that decision, the Board concluded that Michael A. Boss, John H. Kenten, John S. Emtage, and Clive R. Wood (collectively "Celltech's inventors") were entitled to priority over Shmuel Cabilly, Herbert L. Heyneker, William E. Holmes, Arthur D. Riggs, and Ronald B. Wetzel (collectively "Genentech's inventors") with respect to the invention defined by the interference count, which corresponded to claims 1-18 of U.S. Patent No. 4,816,397.

Pursuant to the settlement agreement between the parties, and pursuant to Rule 54(b) of the Federal Rules of Civil Procedure, the Court orders and adjudges that the following shall occur simultaneously:

1. The Court directs the PTO to vacate the PTO's decision in *Cabilly, et al. v. Boss, et al.*, Patent Interference No. 102,572.

2. The Court directs the PTO to revoke and vacate United States Patent No. 4,816,397, issued March 28, 1989 to *Boss, et al.*

3. The Court directs the PTO to grant and issue to Genentech inventors (with Genentech as the assignee), with the issue date being the same of revocation of the United Sates Patent No. 4,816,397, a United States patent having thoses claims 101-120 that were allowed by the PTO in Genentech's pending United States Patent Application No. 07/205,419, which is a continuation of Genentech's United States Patent Application No. 06/483,457 filed April 8, 1983.

The Court shall retain jurisdiction over this matter pending the PTO's compliance with the above orders and judgment. If for any reason the PTO does not comply with the orders set out above, then those orders, this Judgment, and the Order regarding resolution of the interference shall be vacated, and shall have no force and effect, and shall not be relied upon by any person for any purpose, and Genentech and Celltech shall promptly proceed to arbitration as provided in the Settlement Negotiation and Alternative Dispute Resolution Agreement between Genentech and Celltech dated September 18, 2000.

The parties shall bear their own respective attorneys' fees and costs.

IT IS SO ADJUDGED

Dated: March 16, 2001

By: /s/ Maxine M. Chesney
United States District Judge

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Jan. 14, 2004]

Case No. CV 03-2567 MRP

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

AMENDED MEMORANDUM OF DECISION

Re: Defendant Celltech's Motion for Judgment on the Pleadings and Defendant Genentech's Motion for Summary Judgment

On September 30, 2003, Plaintiff Celltech R&D Ltd. ("Celltech") filed a Motion for Judgment on the Pleadings. On October 31, 2003, Genentech, Inc. ("Genentech") filed a Motion for Summary Judgment on Plaintiffs' Antitrust Claims. The Court heard oral argument on December 15, 2003 and took these matters under submission.

BACKGROUND

I. SUMMARY OF THE DISPUTE

This dispute deals with patents claiming a method of producing monoclonal antibodies utilizing recombinant DNA technology. Plaintiff MedImmune is a biotechnology company whose most successful product is Synagis, a drug used to prevent respiratory syncytial virus in children. The Defendants are two biotechnology companies, Celltech and Genentech, and a nonprofit organization, City of Hope. MedImmune's Synagis product utilizes the monoclonal

antibody production techniques covered by the patents at issue. The patent for this technology was originally owned by Celltech, but following the resolution of a priority dispute the technology is now claimed by a patent that has been assigned to Genentech and City of Hope.[1]

MedImmune alleges that Celltech and Genentech illegally resolved the priority dispute between them in a manner that required neither Celltech nor Genentech to give up anything, but that was designed to cause a real loss to others in the industry. Celltech had a patent on the technology at issue that was due to expire in 2006. (Am. Comp. ¶ 13). As part of their settlement, Celltech ceded priority to Genentech. (*Id.* ¶ 12). Genentech then obtained a patent over essentially the same technology; that patent is due to expire in 2018. (*Id.* ¶ 17, ¶ 123). MedImmune claims that this agreement had the effect of creating a 29-year patent monopoly over this technology. (*Id.* ¶ 13).

II. UNDISPUTED FACTS

The essential facts are uncontroverted. *See* Plaintiff MedImmune, Inc's Statement of Genuine Issues of Material Fact and Responses to Proposed Conclusions of Law in Opposition to Genentech, Inc.'s Motion for Summary Judgment (filed under seal November 17, 2003).

A. Cabilly and Boss Patents

On April 8, 1983 Genentech filed a U.S. patent application; this patent issued on March 28, 1989 as U.S. Patent No. 4,816,567 with Shmuel Cabilly as the first inventor (the "Cabilly" patent). On November 14, 1984, Celltech filed an application that issued as U.S. Patent No. 4,816,397 on March 28, 1989 with Michael A. Boss as the first inventor (the

[1] References to "Genentech" in the remainder of this memorandum refer to both Genentech and City of Hope.

"Boss" patent). Genentech had a continuation application pending that claimed the benefit of its original April 8, 1983 application date (the "New Cabilly application"). This New Cabilly application was amended to restate the claims of the Boss patent.

B. Interference

Genentech advised the United States Patent and Trademark Office (PTO) of the conflict between the Boss patent and Genentech's pending New Cabilly application. On February 28, 1991, the PTO's Board of Patent Appeals and Interferences ("Board") declared Patent Interference No.102,572 between the Boss patent and Genentech's pending continuation application. On August 13, 1998, the Board awarded priority to Celltech. *Cabilly v. Boss*, 55 U.S.P.Q.2d 1238 (Bd. Pat. App. & Interf. 1998).

C. § 146 Action

On October 9, 1998, Genentech commenced an action under 35 U.S.C. §146 ("the § 146 action") to overturn the Board's priority determination. During the § 146 action, Genentech produced a draft patent application that had not been produced during the interference proceeding before the PTO.

Genentech filed a summary judgment motion in the § 146 action. On July 28, 2000 the Honorable Maxine M. Chesney, United States District Judge for the Northern District of California, heard argument on Genentech's motion for summary adjudication. Judge Chesney denied Genentech's summary judgment motion on the ground that a triable issue of fact existed.

D. Settlement of the § 146 Action

On the day of the summary judgment hearing, Judge Chesney stated that the parties should consider alternative

dispute resolution or private mediation. Genentech and Celltech engaged in mediation conducted by a retired judge in an effort to resolve the § 146 proceeding. Genentech and Celltech entered into the "Settlement Agreement between Genentech, Inc. and Celltech Chiroscience Limited" ("Settlement Agreement") on March 2, 2001. On the same day, Genentech and Celltech also entered into the "Amended and Restated License Agreement between Genentech, Inc. and Celltech Chiroscience Limited" ("ARLA").

On March 6, 2001, Genentech and Celltech filed a Notice of Settlement and Joint Request for Entry of Settlement Instruments, a Proposed Order Regarding Resolution of Interference ("Proposed Order"), and a Proposed Judgment. On March 14, 2001, Celltech and Genentech participated in a telephonic status conference before Judge Chesney. Revised versions of the Proposed Order and Proposed Judgment were subsequently submitted by Celltech and Genentech. The Order and Judgment were executed by Judge Chesney on March 16, 2001.

E. Obtaining the '415 Patent

On June 1, 2001, Genentech filed certified copies of the District Court's Judgment with the PTO Board. *Cabilly v. Boss*, 60 U.S.P.Q.2d 1752, 1755 (Bd. Pat. App. & Interf. 2001). The PTO Board directed Genentech's application to be returned to an Examiner.

On September 13, 2001 Genentech, through its lawyer and its patent agent, submitted documents relating to Genentech's pending application to the PTO and participated in an interview with representatives of the PTO on the same subject. Subsequently, Genentech submitted a Supplemental Information Disclosure statement to the PTO and, on October 4, 2001, participated in an additional interview with representatives of the PTO.

On December 18, 2001, the PTO issued Genentech's pending continuation application as United States Patent No. 6,331,415B1 (the the "New Cabilly" patent).

F. MedImmune Files Suit

MedImmune filed its initial Complaint in this case on April 11, 2003. On August 13, 2003, Plaintiff MedImmune, Inc. served its First Amended Complaint ("Am. Comp."); its Initial Disclosures were served on August 21, 2003.

LEGAL STANDARD

Although Celltech's and Genentech's motions both rely on the *Noerr-Pennington* doctrine, Celltech's motion is based on Rule 12(c) of the Federal Rules of Civil Procedure (FRCP), whereas Genentech's is a summary judgment motion made under FRCP Rule 56(c). This Court has considered the same evidence in consideration of each motion, thus both motions will be treated as motions for summary judgment. Rule 12(c) explicitly permits this: "If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment . . .". FRCP, Rule 12(c); *see Hal Roach Studios*, 896 F.2d 1542, 1550 (9th Cir. 1989) ("judgment on the pleadings is improper when the district court goes beyond the pleading to resolve an issue; such a proceeding must properly be treated as a motion for summary judgment").

Summary judgment is appropriate when the submissions show that "there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as matter of law." FRCP Rule 56(c); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-26 (1986). For the purposes of this motion, MedImmune is entitled to all reasonable inferences that may be drawn from the evidence it cites. *Eisenberg v. Ins. Co. of N. Am.*, 815 F.2d 1285, 1289 (9th Cir. 1987) ("[T]he non-

moving party's evidence is to be taken as true and all inferences are to be drawn in the light most favorable to the non-moving party."). Furthermore, if MedImmune adduces direct evidence of a genuine issue of fact, such evidence may not be weighed against the Defendants' evidence but must be submitted to the trier of fact for resolution. *Id.*

ANALYSIS

The Defendants ask this Court to find that the *Noerr-Pennington* doctrine bars MedImmune from pursuing its federal antitrust claims (Counts 5 and 6 of the Amended Complaint), state law antitrust claims (Counts 8 and 9), and the state unfair competition claim (Count 10).

The parties agree that California law follows *Noerr-Pennington*, and thus that a decision as to the *Noerr-Pennington* issues will resolve the question of immunity to MedImmune's Cartwright Act and unfair competition claims as well as the Sherman Act claims. Consequently, this discussion focuses on whether the *Noerr-Pennington* doctrine applies to the facts of this case as pled or otherwise established.

I. The *Noerr Pennington* Doctrine

A. State Action Immunity: The Basis for *Noerr-Pennington*

The *Noerr-Pennington* doctrine essentially grants antitrust immunity to parties engaged in petitioning activities. This doctrine has its basis in the state action immunity doctrine—the idea that the government cannot be held liable for anticompetitive acts because the Sherman Act prohibits only those anticompetitive conditions that are sought to be or are created by "individuals or combinations of individuals or corporations." *Standard Oil Co. v. United States*, 221 U.S. 1, 51-62 (1911). States cannot be held liable under the Sherman Act because "nothing in the language of the Sherman Act or in its history suggests that its purpose was to restrain a state

or its officers or agents from activities directed by its legislature." *Parker v. Brown*, 317 U.S. 341, 351 (1942).

B. Antitrust Immunity for Petitioning Activities

The corollary to the state action immunity doctrine is the idea that the conduct of private individuals petitioning the government for anticompetitive action can not be restricted by the antitrust laws, an idea that is known as the *Noerr-Pennington* doctrine.

1. Establishing Petitioning Immunity

The competition between railroads and the trucking Industry over long-distance transportation of freight gave the Supreme Court its first opportunity to consider whether antitrust liability could result from attempting to influence the government to pass anticompetitive laws. *Eastern R.R. Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961). In *Noerr* the trucking industry sought relief under the antitrust laws when a consortium of railroad executives conducted a campaign to sully the image of the trucking industry and obtain the passage of laws restricting freight trucking. 365 U.S. at 129-32. The *Noerr* Court recognized that "no violation of the Act can be predicated upon mere attempts to influence the passage or enforcement of laws" and ruled that the railroads could not be held liable for the effects of their campaign. *Id.* at 141-43. The Court held that the Sherman Act does not prohibit two or more persons from associating together in an attempt to persuade the legislature or the executive to take particular action with respect to a law that would produce a restraint or a monopoly"). *Id.* at 136.

Although *Noerr* dealt only with petitioning lawmakers, later cases made it clear that petitioning the executive and judicial branches was protected as well: "the right to petition extends to all departments of the Government." *California Motor Transport Co. et al. v. Trucking Unlimited et al.*, 404 U.S. 508, 510 (1972) (applying *Noerr* immunity to peti-

tioning the courts);[2] *United Mine Workers of America v. Pennington et al.*, 381 U.S. 657, 671 (1965) (applying *Noerr* immunity to petitioning an executive official).[3]

2. Justification for Petitioning Immunity

The Noerr Court stated two reasons for concluding that Congress did not intend petitioning activities to be regulated by the Sherman Act.

First, the Court noted that "the whole concept of representation depends on the ability of the people to make their wishes known to their representatives." *Noerr*, 365 U.S. at 137. The imposition of antitrust liability for attempts to influence government could chill those communications and would thus be detrimental to democratic government. *Id.* To hold that people cannot freely inform their representatives of their wishes would impute to Congress an attempt to regulate political activity, a purpose that the Court found unsupported by the legislative history of the Sherman Act. *Id.*

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[2] In *California Motor Transport*, a group of highway carriers attempted to resist and defeat a competitor group's applications for operating rights by seeking reviews and appeals of agency and court decisions on the applications. 404 U.S. at 509. The Court found that "the right of access to the courts is indeed but one aspect of the right of petition" and thus that "it would be destructive of rights of association and of petition to hold that groups with common interests may not, without violating the antitrust laws, use the channels and procedures of state and federal agencies and courts to advocate their causes and points of view respecting resolution of their business and economic interests *vis-a-vis* their competitors." *Id.* at 510-11.

[3] In *Pennington*, the Court considered the legality of a joint effort by a coal workers union and large companies in the industry to obtain establishment from the Secretary of Labor of a minimum wage that would drive smaller companies out of the industry. *United Mine Workers of America v. Pennington et al.*, 381 U.S. 657, 660 (1965). The Court found that *Noerr* made it clear that the union and large companies could not be held liable for any injuries the plaintiff suffered from the action of the Secretary of Labor. *Id.* at 671.

Second, the Court recognized that the First Amendment's right of petition could be violated by imposing antitrust liability on petitioning activities. *Id.* at 138. The Court found that it could not "lightly impute to Congress an intent to invade these freedoms." *Id.*

C. Petitioning for the New Cabilly Patent

The *Noerr-Pennington* doctrine confers immunity where petitioners "attempt to persuade [the government] to take particular action with respect to a law that would produce a restraint or monopoly." *Noerr* 365 U.S. at 136. In this case, the "particular action(s)" that the Defendants sought that would "produce a restraint or monopoly" were the resolution of priority and the issuance of the New Cabilly patent.

As MedImmune suggested in oral argument, there were two basic steps necessary to the issuance of the New Cabilly patent: 1) establishing priority and 2) resolving the other patent issues before the PTO. As is discussed below, this Court finds that petitioning was involved in each of these two steps.[4] Consequently, this Court finds that the *Noerr-*

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[4] Had petitioning been involved in only one of these two steps, immunity would still have been conferred. In prior cases applying the *Noerr-Pennington* doctrine, including *Noerr* itself, only one petitioning activity has been involved. Had only one of the two "prongs" involved petitioning, immunity would still preclude MedImmune's antitrust claims because either through resolving priority or resolving other patent issues, petitioning would still have been involved in obtaining the New Cabilly patent. Immunity protects not only the petitioning activity, but other related activity as well:

> The *Noerr* Court also rejected the proposition that petitioning immunity was limited to injuries flowing directly from governmental action. It held that the railroads were also shielded from liability for the harm the truckers suffered in their relationships with their customers. In the Court's view, that injury was 'incidental' to the defendants' campaign to influence legislation. To impose liabil-

Pennington doctrine protects the Defendants from antitrust liability. Summary judgment on the antitrust and related state causes of action is therefore GRANTED in favor of the Defendants.

II. PRIORITY

In August of 1998 the PTO's Board awarded priority to Celltech. *Cabilly v. Boss*, 55 U.S.P.Q. 1238 (Bd. Pat. App. & Interf. 1998). Overturning this priority decision was a necessary step to obtaining the New Cabilly patent.

A. MedImmune's Proposed Course of Action

MedImmune contends that priority could have been resolved without government action and that *Noerr-Pennington* immunity does not attach simply because the Defendants chose to resolve priority through Judge Chesney's Court. According to MedImmune, Celltech needed only to file a disclaimer under 35 U.S.C. § 253 to cancel the claims of the Boss patent. Then, according to MedImmune, the PTO would have automatically issued the New Cabilly patent. This argument is both inconsequential and inaccurate.

1. The Availability of Non-governmental Alternatives

MedImmune has failed to cite, and this Court has been unable to find, any law to support the proposition that immunity is unavailable if the anti-competitive result *could* have occurred without government action, even though the result does not actually occur that way. "[W]here a restraint upon trade or monopolization is the result of a valid

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ity for such incidental effects would 'be tantamount to outlawing' the petitioning activity itself.

Sessions Tank Liners, Inc. v. Joor Manufacturing, Inc., 17 F.3d 295, 299 (9th Cir. 1994). Even if only one "prong" were held to be protected petitioning activity, the Defendants' involvement in the other "prong" would likely be incidental activity as described in *Joor*.

governmental action, as opposed to private action, those urging the governmental action enjoy absolute immunity from antitrust liability for the anti-competitive restrain." *Joor*, 17 F.3d at 301 (quoting *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 498 (1988), and *Noerr*, 365 U.S. at 136). The antitrust immunity that the government enjoys, and that petitioners who urge government action correspondingly enjoy, is not dependent on their being a non-governmental way to have achieved the anti-competitive result; it depends simply on whether the alleged violation actually involved petitioning.

2. MedImmune's Proposed Alternative

It is simply not true that the New Cabilly patent would have issued in any ministerial way had Celltech utilized § 253 to cancel the claims of the Boss patent. Even if Celltech had cancelled its claims, the Board's outstanding priority decision would still have needed to be overturned.[5]

MedImmune argues that had Celltech cancelled the claims of the Boss patent, the patent would have been treated as never having existed. MedImmune claims that PTO procedure would then have provided for an entry of judgment against Celltech. It is true that when a party involved in an interference claims under § 253 such that all claims corresponding to the count(s) at issue in the interference are deleted, the Board *may* enter judgment against the party. 37

[5] As is discussed further in Part II, even if MedImmune's argument were correct and priority could have been resolved without government action, petitioning was still a necessary part of the application for the New Cabilly patent. As is illustrated by the PTO's refusal to obey Judge Chesney's order and issue the New Cabilly patent once Judge Chesney had declared Genentech the winner of the priority dispute, the PTO does not act ministerially in issuing patents, even when priority has been resolved. *Cabilly v. Boss*, 60 U.S.P.Q. 1752, 1756 (Bd. Pat. App. & Interf. 2001).

CFR § 1.662. However, this is still a matter of discretion, and nothing in the regulations suggests that it is done in a ministerial or automatic way.[6]

No law supports MedImmune's contention that *Noerr-Pennington* immunity does not attach to petitioning if the petitioner's desired result could have been accomplished through means not involving petitioning. Even if this proposition had support in the law, it would not help MedImmune in this case because there was simply no non-petitioning means for priority to be resolved, or for the PTO to evaluate other patent issues. The process leading up to the New Cabilly patent necessarily involved petitioning.

As petitioning would have had to have occurred for the New Cabilly patent to issue even if the Defendants had followed the route MedImmune proposed, and as no law suggests that whether non-petitioning alternatives are available is even relevant, the more important question is whether the petitioning actually involved in resolving priority confers *Noerr-Pennington* immunity.

B. Judge Chesney's Order

The route that the Defendants actually chose to resolve priority involved petitioning. MedImmune argues that merely asking a Judge to approve settlement is not petitioning sufficient to confer immunity, but even if they are right on this point of law, those facts are not what occurred in this

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[6] That § 1.662 is not ministerial provides further support for the idea that an inquiry into whether non-governmental alternatives are available is meaningless. Even if the § 253 procedure had been employed, there is no guarantee that this would have resolved priority. This Court cannot fault the parties for proceeding in a manner that had more certainty—petitioning Judge Chesney for an Order that the Board was willing to accept as determinative as to priority. *See Cabilly v. Boss*, 60 U.S.P.Q.2d 1752, 1757 (2001).

case. MedImmune further argues that even if approval of a settlement does confer immunity, the availability of immunity depends in some way on the process involved in the approval. That is simply not true. Finally and most importantly, MedImmune contends that misrepresentations to Judge Chesney nullify any immunity that might otherwise have attached. This Court finds that no misrepresentations have been pled that would allow this Court to conclude that the Defendants have lost their right to *Noerr-Pennington* immunity.

1. Approving a Settlement Agreement

The parties seem to agree that a court's stamp of approval will not immunize private anti-competitive agreements; genuine petitioning is necessary for *Noerr-Pennington* immunity to apply. Genentech concedes that settlements that merely require compulsory filings, ministerial agency actions, or inconsequential court orders such as Rule 41(a) dismissals do not raise a *Noerr-Pennington* defense.

This case can be distinguished from those that do not raise *Noerr-Pennington* questions because this is not a case of the government acting in some way on an agreement that is independently anti-competitive, but the very anti-competitiveness of the agreement depends on the government exercising its discretion to create an anti-competitive result. MedImmune attempts to characterize the settlement agreement itself as anti-competitive, and argues that Judge Chesney's role in approving the settlement cannot immunize it. This is a mischaracterization of the legal effect of the agreement and the role of the government in creating the alleged antitrust violations of which MedImmune complains. This is not a case of an anticompetitive private agreement receiving immunity because it passed through government hands in some ministerial way. Here, the very anti-competitiveness of the agreement depended on the government

exercising its independent power to decide priority and issue the New Cabilly patent.[7]

The Defendants in this case did not merely present their settlement to Judge Chesney for approval; they sought a Judgment and an Order as well. The documents that she signed accomplished results, such as overturning the Board's priority decision, that could not have been accomplished through private agreement. It was these documents—the results of the Defendants' petitioning and Judge Chesney's order—that resolved the issue of priority.

2. Judge Chesney's Process

It does not matter whether Judge Chesney ever reached a "considered, substantive judgment," (to use MedImmune's phrase), that Genentech deserved priority. To evaluate this question would require deconstructing the decision-making process, which is exactly what the Ninth Circuit forbade in *Joor*. 17 F.3d at 300. Whether the decisionmaker involved made a "considered, substantive" judgment has not been evaluated in prior cases applying *Noerr*, and this Court declines to add that requirement to the *Noerr-Pennington* doctrine. It does not matter how or why Judge Chesney reached her decision. It matters only that she had the discretion to resolve priority in favor of Genentech and she did so.

3. Alleged Misrepresentation

MedImmune's most compelling attempt to avoid *Noerr-Pennington* immunity is its claim that misrepresentations to the Court preclude Noerr immunity. Where misrepresentations to a court "deprive the litigation of its legitimacy" they

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[7] MedImmune makes one antitrust arguement that does not depend on the issuance of the New Cabilly patent. This argument—that Genentech and Celltech engaged in illegal price fixing—is addressed in Part III of this Analysis.

can cause a party to lose *Noerr-Pennington* immunity. *Kottle v. Northwest Kidney Centers*, 146 F.3d 1056, 1060 (9th Cir. 1998) (noting that misrepresentations to the court may cause litigation to be deemed a sham, and thus fall within an exception to *Noerr-Pennington* immunity). MedImmune alleges three misrepresentations to the Court.

First, MedImmune claims that the Defendant's statement to the Court that Genentech's New Cabilly Patent had priority over the Boss patent was a misrepresentation. This was, however, the key issue in the litigation—any settlement agreement had to make a representation one way or the other on this issue and that representation was sure to be contradictory to a position that one of the parties had taken earlier in the litigation. *Kottle* indicates that disputed issues from the underlying litigation cannot be recast as misrepresentations. 146 F.3d at 1063.

Second, MedImmune asserts that the Defendants' statement that the New Cabilly patent did not have defects that should bar its issuance was a misrepresentation. It is not clear from the facts that this statement was a misrepresentation—the fact that the PTO issued the New Cabilly patent suggests that it was at least not a gross misrepresentation. Even if MedImmune could establish that this was a misrepresentation, it would not change the result. The PTO did not rely on Judge Chesney's determination that the New Cabilly patent should issue, thus MedImmune could not have sustained injury from this order. The Defendants consequently have no reason to claim immunity for petitioning for this order, and there is therefore no consequence to a determination that a misrepresentation precipitated the order.

Third, MedImmune alleges that the Defendants misrepresented the law by suggesting to Judge Chesney that Genentech should be granted priority if it demonstrated conception. As students learn in the first days of any patent law class, priority is awarded to the first to reduce to practice, unless the

first to conceive works diligently to reduce the idea to practice. This Court must assume that Judge Chesney was not misled by any statement to the contrary. *Walton v. Arizona*, 497 U.S. 639, 653 (1990)("Trial judges are presumed to know the law and to apply it in making their decisions"), cited in *Beaty v. Stewart*, 303 F.3d 975, 986.(9th Cir. 2002).

II. PTO PROSECUTION

The parties agree that attempts to obtain the issuance of a patent from the PTO are ordinarily covered by *Noerr-Pennington*. However, a patentee may be subject to antitrust liability for enforcing a patent obtained through knowing and willful fraud on the patent office. *Walker Process Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965); *Nobelpharma AB, et al. v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (discussing *Walker Process* fraud and the sham exception to *Noerr-Pennington* as two ways a patentee could be found liable in antitrust).[8] MedImmune argues that in this case the Defendants committed fraud on the patent office that prevents *Noerr-Pennington* immunity from attaching. This argument fails because in its Amended Complaint, MedImmune does not plead fraud.

MedImmune's *Walker Process* theory is not supported in the pleadings. Although MedImmune argues that it "asserts with reference to specific facts, at least forty times, that Genentech's omissions and misrepresentations were intentionally made with deceptive intent," Opposition at 18, a review of the Amended Complaint reveals that it is inequitable conduct, not fraud, that appears in the pleadings. Fraud

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[8] Neither party has alleged that the sham exception to the *Noerr-Pennington* doctrine applies in this case. MedImmune does allege that the Defendants made misrepresentations to Judge Chesney, and misrepresentations can make litigation into a sham, *Kottle*, 146 F.3d at 1060, but Part I(C) of this Analysis explains that misrepresentations have not be adequately alleged.

(as that term is meant in *Walker Process*) and inequitable conduct are different legal concepts, and it is simply not the case that inequitable conduct pleadings can be read as affirmatively pleading fraud for all purposes. MedImmune has not pled facts sufficient to support *Walker Process* fraud.

A. Distinguishing Inequitable Conduct from Fraud

There is a significant difference between *Walker Process* fraud and inequitable conduct, a state of law that was highlighted to this Court by Plaintiff earlier in this litigation.[9] The Federal Circuit discussed this distinction in *Nobelpharma*, where it noted that "inequitable conduct is a broader, more inclusive concept than the common law fraud needed to support a *Walker Process* counterclaim," and that "[i]nequitable conduct in fact is a lesser offense than common law fraud, and includes types of conduct less serious that "knowing and willful" fraud. 141 F.3d at 1069; *see* also *Norton v. Curtiss*, 433 F.2d 779, 793 (C.C.P.A. 1970) (contrasting inequitable conduct with conduct "sufficiently reprehensible so as to carry with it the consequences of technical fraud").

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[9] When filing its Amended Complaint, MedImmune assured this Court that it was making changes to its inequitable conduct claim to "make it consistent with the Court's Order dated August 11, 2003." The August 11, 2003 Order to which MedImmune refers granted Genentech's Motion to Dismiss an inequitable conduct claim but allowed MedImmune leave to amend it. In defending against this Motion to Dismiss, MedImmune argued that the heightened pleading standard of FRCP Rule 9(b) applied only to fraud claims. MedImmune took pains to distinguish its inequitable conduct claim from a fraud claims. *See* Plaintiff MedImmune, Inc's Opposition to Motion by Defendant Genentech, Inc. to Dismiss the Third and Eleventh Causes of Action (filed July 14, 2003) at 9. It now appears that MedImmune is trying to argue that in amending its inequitable conduct claim, it converted it into a fraud claim. This argument is both disingenuous and, as is discussed in more detail above, not supported by the pleadings.

The *Nobelpharma* court contrasted the nature of the claims and the remedies available for fraud, as that term is meant in *Walker Process* with the claims and remedies for inequitable conduct. The court noted that inequitable conduct is an equitable defense, whereas fraud is an affirmative claim. 141 F.3d at 1070. It also compared the treble damages available in antitrust with the remedies of patent unenforcability and possibly attorney's fees that are available for inequitable conduct. *Id.*

B. Pleading Fraud

MedImmune alleges that Genentech acted fraudulently by 1) failing to alert the PTO to the enablement problems relating to the refolding aspect of the claimed invention, 2) failing to disclose its prior inconsistent position with respect to a material prior art reference known as the Vallé reference, 3) failing to disclose certain anticipatory prior art about which it allegedly knew and 4) burying anticipatory prior art in the voluminous documents that composed its submission. Even if this Court were willing to look past the disingenuousness of MedImmune's assertation that what the parties-and this court were told was an inequitable conduct claim has morphed into a fraud claim, MedImmune's pleadings do not allege facts that, if proved, would allow this Court to conclude that the elements of *Walker Process* fraud had been satisfied.

In *Norton*, the court that preceded the Federal Circuit explained the elements of what the *Nobelpharma* court called "'fraud' as that term was used by the Supreme Court in *Walker Process*," 141 F.3d at 1069:

> traditionally, the concept of "fraud" has most often been used by the courts, in general, to refer to a type of conduct so reprehensible that it could alone form the basis of an actionable wrong (e.g., the common law action for deceit.) That narrow range of conduct, now frequently referred to as 'technical' or 'affirmative'

> fraud, is looked upon by the law as quite serious. Because severe penalties are usually meted out to the party found guilty of such conduct, technical fraud is generally held not to exist unless the following indispensable elements are found to be present: 1) a representation of a material fact, 2) the falsity of that representation, 3) the intent to deceive or, at least, a state of mind so reckless as to the consequences that it is held to be the equivalent of intent (scienter), 4) a justifiable reliance upon the misrepresentation by the party deceived which induces him to act thereon, and 5) injury to the party deceived as a result of his reliance on the misrepresentation.

Norton, 433 F.2d at 792-93, cited in *Nobelpharma*, 141 F.3d at 1069-70.

To fulfill the requirements of *Walker Process*, "a misrepresentation or omission must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent." *Nobelpharma*, 141 F.3d at 1070. This standard is a difficult one to meet, as the *Nobelpharma* court explains:

> A finding of *Walker Process* fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. Moreover, unlike a finding of inequitable conduct, . . . a finding of *Walker Process* fraud may not be based upon an equitable balancing of lesser degrees of materiality and intent. Rather, it must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e. that the patent would not have issued but for the misrepresentation or omission.

141 F.3d at 1070-71 (internal citations omitted). MedImmune's pleadings fail to fulfill the requirements of *Walker Process* fraud, because they suggest neither "independent or

clear evidence of deceptive intent" nor that "the patent would not have issued but for the misrepresentation or omission" (i.e. reliance).

In fact, the PTO is presumed to be aware of the references before it, which would include the court documents discussing enablement problems, the Vallé reference, and the other prior art that was submitted, even if it was buried. *See American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (Fed. Cir. 1984) (noting that a PTO examiner is presumed to have considered the documents submitted). Even inequitable conduct cannot be found on the basis of a reference that was cited to the examiner. *Fiskars, Inc. v. Hunt Manufacturing Co.*, 221 F.3d 1318, 1327 (Fed. Cir. 2000)("An applicant cannot be guilty of inequitable conduct if the reference was cited to the examiner, whether or not it was a ground of rejection by the examiner").

As for references that were not before the PTO, omissions cannot be fraudulent absent evidence of fraudulent intent. *Nobelpharma* states: "for an omission such as failure to cite a piece of prior art to support a finding of *Walker Process* fraud, the withholding of the reference must show evidence of fraudulent intent. A mere failure to cite a reference to the PTO will not suffice." 141 F.3d at 1071. MedImmune does not plead facts that would support a finding of fraudulent intent.

MedImmune cannot show that the PTO relied on alleged misrepresentations about references that were before it because the examiner is presumed to have independently considered the references, and MedImmune cannot base a *Walker Process* claim on the omission of references without alleging independent evidence of deceptive intent. Thus even if each of the allegations of MedImmune's Amended Complaint were true, they would be insufficient to support a claim of *Walker Process* fraud.

III. PRICE FIXING

MedImmune has one antitrust argument that does not implicate *Noerr-Pennington* considerations. This argument is based on the ARLA between Celltech and Genentech, and essentially claims that the ARLA was an illegal price fixing agreement. The ARLA provides that Celltech will receive royalty payments from Genentech that are to be paid from the royalties that Genentech obtains from third parties, including MedImmune. Because the ARLA provides that Genentech will "use best efforts" to charge these third parties at least certain minimum royalties, MedImmune asserts that the ARLA is a price-fixing agreement.

There are at least two problems with MedImmune's theory: 1) price-fixing is not pled in the Amended Complaint and 2) MedImmune would not have standing to make this price-fixing claim even if it were in the Amended Complaint.[10]

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[10] In addition to these two preliminary problems, this Court's review of the ARLA leads to the conclusion that price-fixing is not a part of the agreement. Section 3.02 of the agreement lists "Royalties Payable by Genentech for Third Party Products." The first five subparts of §3.02 list specific products for which Celltech was receiving royalties under the Boss patent, and specifies the royalty rate that Genentech would pass-through for sales of that product once Genentech owned the patent to the technology. ARLA §3.02(a)-(e), Winters Declaration, Ex. 14, pp. 11-14 (filed under seal October 31, 2002).

The paragraph about which MedImmune complains provides:

> Genentech shall be obligated to pay Celltech the royalties specified in paragraphs 3.02(a)-(e) on Net Sales by a third party licensee or sublicensee of a particular Antibody product only if the amount of payments received by Genentech in a Calendar Quarter from its third party licensee or sublicensee for such product, after deduction of the portion thereof that Genentech is obligated to pay to the City of Hope, equals or exceeds the royalty owed to Celltech in such Calendar Quarter for such Net Sales. Genentech shall, and Genentech shall require that its Affiliates shall, i) use best efforts to impose upon all third parties which are the licensees and sublicensees

MedImmune's price-fixing theory does not appear in the Amended Complaint. The Amended Complaint does state that the settlement is "illegal and anticompetitive" under either the per se or rule of reason theory. Am. Comp. ¶¶ 9, 170-72. It does not, however, allege price fixing in any less general way. MedImmune has not alleged facts in its Amended Complaint that would, if true, suggest that the settlement involved price fixing.

Even if MedImmune had alleged price-fixing in the Complaint, it is difficult to see how the paragraph about which MedImmune complains (*see* n.8) affects MedImmune. The only MedImmune product affected the §3.02 of the ARLA is Synagis, and the parties agree that MedImmune signed a license agreement with Genentech regarding Synagis prior to entering the settlement agreement or the ARLA. As MedImmune's royalties for Synagis are established by this licensing agreement, MedImmune would be unaffected by any price-fixing in the ARLA even if it were adequately alleged. MedImmune claims to be worried about its other "pipeline products" but the plain language of the ARLA and Genen-

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with respect to the Antibody products referred to in paragraphs 3.02(a)-(e) an obligation to pay to Genentech (or the relevant Affiliate) an amount at least sufficient to meet the royalty obligations set out in paragraphs 3.02(a)-(e), and ii) use reasonable and diligent efforts in good faith to collect such amounts from such third parties.

ARLA §3.02(f), Winters Dec. Ex. 14 pp.14. The paragraph continues on to make provisions that would take effect if Genentech did not collect from third parties royalties in the amounts promised to Genentech. This include passing-through the lesser royalty amount and accruing the remainder for payment at a later time. *Id.* at pp. 14-15. This paragraph requires Genentech to attempt to maintain at least the royalty rates that Celltech was receiving so that Celltech receives the consideration it is expecting from ceding priority, but it does not set a minimum royalty rate at which a license to the Cabilly Patent will be set. Although this Court declines to decide the price fixing issue because of the pleading and standing problems discussed in the text, it is unlikely that such a claim would be successful.

tech's representations in oral argument make it clear that § 3.02 of the ARLA does not cover any MedImmune product, current or future, other than Synagis.

MedImmune has not pled price-fixing, and has no standing to plead that § 3.02 of the ARLA constitutes price-fixing. Consequently, MedImmune can not establish a antitrust claim based on price-fixing.

CONCLUSION

Where a plaintiff "fail[s] to prove that its injuries result from anything other than governmental action," *Noerr-Pennington* immunity will attach. *Joor*, 17 F.3d at 296. With the exception of the price fixing argument dismissed in Part 3 above, MedImmune has not pled an injury that was the result of the Defendants' settlement agreement. In the absence of government action in resolving priority and issuing the New Cabilly patent, MedImmune would have suffered no harm from the Defendants' settlement. Because the alleged "restraint upon trade or monopolization is the result of valid governmental action, as opposed to private action," *Noerr-Pennington* immunity applies. *Joor*, 17 F.2d at 301.

Based upon the fact that *Noerr-Pennington* immunity bars MedImmune's antitrust and related state claims, and in light of MedImmune's failure to adequately plead any antitrust violation (such as price-fixing in the ARLA) that is not barred by *Noerr-Pennington*, summary judgment for the Defendants is hereby GRANTED with respect to the fifth, sixth, seventh, eighth, ninth, and tenth causes of action in the First Amended Complaint.

IT IS SO ORDERED

DATED: January 12, 2004

/s/ Mariana R. Pfaelzer
Honorable Mariana R. Pfaelzer
United States District Judge

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Feb. 18, 2004]

Case No. CV 03-2567 MRP

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

MEMORANDUM OF DECISION
RE: Celltech's Motion For Entry of Final Judgment

On January 20, 2003, Defendant Celltech R&D Ltd. ("Celltech") filed a Motion for Entry of Final Judgment ("Motion"). Having determined that oral argument will not assist the Court in considering this motion, this Court hereby vacates the hearing scheduled for February 23, 2004, and GRANTS Celltech's motion.

BACKGROUND

I. The Case

A. Basic Facts

This case involves a technique for using recombinant DNA technology to produce monoclonal antibodies. Plaintiff MedImmune's most successful product, Synagis, requires the use of this technology. MedImmune asserts that the technology at issue was patented by Defendant Celltech, but is now covered by a patent that has been assigned to Defendants Genentech and City of Hope. This, according to MedImmune, had the effect of creating an illegal twenty-nine year patent monopoly.

B. Claims

MedImmune's First Amended Complaint asserts ten claims against three named defendants. First Amended Complaint ("FAC") ¶¶ 131-215. The first claim is for declaratory judgment of rights and obligations under MedImmune's license agreement with Genentech. FAC ¶¶ 131-33. Three claims are patent claims (invalidity, unenforceability, and non-infringement). FAC ¶¶ 134-64. The final six claims are state and federal antitrust and unfair competition claims. FAC ¶¶ 165-201.

C. Parties

Plaintiff MedImmune brings claims against three defendants. Genentech, Inc. ("Genentech") is a defendant as to every claim. FAC ¶¶ 131-201. City of Hope is a defendant only as to the patent claims. FAC ¶¶ 134-64 (Second, Third, and Fourth Causes of Action). Celltech, the moving party in this motion, is a defendant as to most of the antitrust and unfair competition claims, but none of the contract or patent claims. *See* FAC ¶¶ 165-180, ¶¶ 186-201 (Fifth, Sixth, Eighth, Ninth, and Tenth Causes of Action).

II. Summary Judgment

This Court recently granted summary judgment against MedImmune on the antitrust and unfair competition causes of action at issue in this case. Memorandum of Decision Re: Defendant Celltech's Motion for Judgment on the Pleadings and Defendant Genentech's Motion for Summary Judgment. ("Summary Judgment Decision") (filed 12/23/03, amended 1/14/04). The antitrust and unfair competition claims against Celltech and Genentech were disposed of by this summary judgment decision. Consequently, there are now no pending causes of action against Celltech.

III. Motion for Entry of Final Judgment

Celltech filed its Motion on January 20, 2003. On February 6, 2004, Genentech joined Celltech's motion. Genentech, Inc.'s Joinder in Celltech's Motion for Entry of Judgment Pursuant to Rule 54(b) ("Genentech Joinder") (filed Feb. 6, 2004). Genentech prefers a single appeal in this case after all issues are resolved and would not have sought a Rule 54(b) judgment absent Celltech's request. Genentech Joinder at 1, 3. However, if Rule 54(b) judgment is entered, Genentech requests that it be entered as to all the antitrust and unfair competition claims, and that Genentech be included as a party in favor of whom final judgment is entered on these claims to avoid the potential for piecemeal appeals. *Id.*

MedImmune consents to Celltech's Motion. MedImmune filed a statement suggesting that this Court decide this Motion after MedImmune's Motion for Leave to Amend has been decided, and indicating that if leave to amend is denied "MedImmune consents to Celltech's 54(b) Motions as it believes that prompt appellate review of these issues is appropriate." Plaintiff MedImmune, Inc.'s Statement in Response to Defendant Celltech R&D Ltd.'s Motion for Entry of Final Judgment (filed Feb. 6, 2004). Thus, with the exception of Genentech's misgivings, this Motion is unopposed.

ANALYSIS

When multiple claims or parties are involved in an action, a district court may enter final judgment as to one or more of the claims or parties prior to the resolution of the entire case. FRCP Rule 54(b). The federal rule states:

> When more than ore claim for relief is presented in an action . . . or when multiple parties are involved, the court may direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just

> reason for delay and upon an express direction for the entry of final judgment.

Id.; see also Sheehan v. Atlanta Int'l Inst. Co., 812 F. 2d 465, 468 (9th Cir. 1987) (finding no abuse of discretion in district court's Rule 54(b) judgment when the court expressly found "no just reason for delay").

An entry of final judgment is appropriate where 1) the judgment is final as to one or more claims and 2) the court properly concludes that there is no just reason for delay. *See W.L. Gore & Assoc. Inc. v. Int'l Medical Prosthetics Research Assoc., Inc.*, 975 F. 2d 858, 861-2 (Fed. Cir. 1992).

I. Finality of Judgment

The statutes governing the courts of appeals limit their jurisdiction to final decisions of the district courts. *See* 28 U.S.C. §1291 (governing most courts of appeals); 28 U.S.C. § 1295(a)(1) (governing the Federal Circuit); *Sears, Roebuck & Co. v. Mackey*, 351 U.S. 427, 435 (1956) (noting that Rule 54(b) "does not relax the finality required of each decision, as an individual claim"). Thus, "[t]he requirement of finality is a statutory mandate and not a matter of discretion." *W.L. Gore*, 975 F.2d at 862. Before entering final judgment, this Court must determine that, according to "traditional notions of finality" and guided by Supreme Court precedent, the judgment is final. *W.L. Gore*, 975 F.2d at 862-64.

A judgment is only final if it is "an ultimate disposition of an individual claim entered in the course of a multiple claims action." *Sears*, 351 U.S. at 436. This Court's summary judgment decision is the ultimate disposition of the antitrust and unfair competition claims that MedImmune brought in this action. After considerable research and consideration, this Court concluded that the *Noerr-Pennington* doctrine applied to bar the antitrust and unfair competition claims against the Defendants. Summary Judgment Decision, at 6-23. MedImmune has been unable to frame antitrust or unfair com-

petition claims that do not hinge on the Defendants' petitioning activities, and is thus unable to assert claims that are not barred by *Noerr-Pennington* immunity.[1] Because the determination that those claims are barred by the *Noerr-Pennington* doctrine "ends the litigation on the merits and leaves nothing for the court to do but execute the judgment" as to those claims this Court's decision that the antitrust and unfair competition claims cannot remain in this case is a final one. *Catlin v. United States*, 324 U.S. 229, 233 (1945).

II. Just Reason for Delay

Appropriate factors for consideration in determining whether there are just reasons for delay include "whether the claims under review were separable from the others remaining to be adjudicated and whether the nature of the claims already determined was such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals." *Curtiss-Wright Corp. v. General Electric Corp.*, 446 U.S. 1, 8 (1980).

A. Separateness of the Claims for Relief

In choosing whether to exercise discretion to enter final judgment as to the antitrust and unfair competition claims, this Court must consider the factual relatedness of those claims to the remaining contract, patent unenforceability, invalidity, and non-infringement claims. *See Cold Metal Process Co. v. United Eng'g & Foundry Co.*, 351 U.S. 445, 452 (1956) (the relationship of the adjudicated claims to the unadjudicated claims is one of the factors which the District

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[1] On or about the same day of this Order, this Court will issue an order denying MedImmune's Motion to File a Second Amended Complaint. Memorandum of Decision re Motion to File Second Amended Complaint (filed 02/17/2004). As is indicated by that Memorandum of Decision, MedImmune's attempts to formulate antitrust and unfair competition claims that avoid the consequences of *Noerr-Pennington* and this Court's order were unsuccessful. *Id.*

Court can consider in the exercise of its discretion). The remaining causes of action (1-4) are not substantially related to those that were the subject of the summary judgment order.

The claim that is potentially the most factually related to the claims resolved by the summary judgment order is MedImmune's patent unenforceability claim. FAC ¶¶ 140-61. In this claim, MedImmune contends that Genentech's patent is unenforceable due to Genentech's alleged inequitable conduct before the PTO.[2] Because part of MedImmune's antitrust claim was based on alleged misrepresentations before the PTO, there may be some factual overlap in these claims. However, any overlap is unlikely to be significant, especially to a court of appeals that will be evaluating whether *Noerr-Pennington* creates immunity, not whether the alleged inequitable conduct creates an antitrust violation.

Even where there is some factual overlap, entry of final judgment may be appropriate if other sufficiently important factors are served. *See Curtiss-Wright*, 446 U.S. at 8, n.2; *Intergraph Corp. v. Intel Corp.*, 253 F.3d 695, 699 (Fed. Cir. 2001) ("Even for claims that arise out of the same transaction or occurrence, sound case management may warrant entry of

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[2] Celltech's statement that this Court "has already held that the inequitable conduct allegations are inadequate to overcome *Noerr-Pennington* immunity" is untrue, and makes no sense. It is true that this Court noted that "attempts to obtain the issuance of a patent from the PTO are ordinarily covered by *Noerr-Pennington*," and found that the exception to this rule—*Walker Process* fraud—did not apply. Summary Judgment Order, 18-23. However, this Court's finding that Genentech's petitioning activity before the PTO cannot be the basis of an antitrust or unfair competition claim in no way precludes MedImmune from arguing that Genentech engaged in inequitable conduct that renders the patent unenforceable. If this Court accepted Celltech's interpretation of the Summary Judgment Order, then it would have to import *Walker Process* into unenforceability analysis, allowing unenforceability claims only when the standards for fraud are fulfilled, and thereby eradicating the concept of inequitable conduct.

partial final judgment.") In this case, a party and a significant portion of easily severable claims were eliminated by the summary judgment order. Entry of final judgment on those claims will allow the *Noerr-Pennington* decision to be heard on appeal if MedImmune chooses to pursue one and will streamline and simplify the resolution of the claims that remain with this Court.

B. Risk of Piecemeal Litigation

Another factor in this Court's decision to enter final judgment on the antitrust and unfair competition claims is consideration of "whether an 'appellate court would have to decide the same issues more than once even if there were subsequent appeals.'" *Curtiss-Wright*, 446 U.S. at 8, *cited in Gore* 975 F.2d at 864. This might be a concern if this Court entered final judgment as to Celltech, but not as to Genentech, because MedImmune could appeal the *Noerr-Pennington* decision as to Celltech right away, and then could appeal the same decision as to Genentech once the entire case was resolved. However, Rule 54(b) allows this Court to enter final judgment not only as to parties whose involvement in the litigation has concluded, but as to claims that have been fully litigated. FRCP Rule 54(b).

This Court's judgment as to the *Noerr-Pennington* issues is final, and there is no reason to delay the parties' ability to appeal this decision if they choose to do so. This Court therefore enters final judgment as to both Celltech and Genentech on the antitrust and unfair competition claims. If MedImmune chooses to appeal the *Noerr-Pennington* decision, they will do so with respect to both Celltech and Genentech and thus the court of appeals will only have to evaluate this Court's *Noerr-Pennington* analysis once.

CONCLUSION

This Court has fully considered and adjudicated the antitrust and unfair competition claims against Celltech and Genentech. As these issues have been eliminated from the case, final judgment is appropriate. *See Cadillac Fairview v. United States*, 41 F.3d 562, 564 n.l (9th Cir. 1994) ("eliminating issues and parties from a case justifies the entry of final judgment on a claim"); *Alcan Aluminum Corp. v. Carlsberg Financial Corp.*, 689 F.2d 815, 817 (9th Cir. 1982) (affirming Rule 54(b) entry of final judgment where all claims against a party have been decided). As there is no reason to delay appeal on those claims, this Court enters final judgment on the fifth, sixth, seventh, eighth, ninth and tenth causes of action.

MedImmune may pursue the remaining claims (determination of contractual obligations, patent unenforceability, patent invalidity and non-infringement) against Genentech (and City of Hope), but Celltech will no longer be involved as a party.

IT IS SO ORDERED

DATED: February 17, 2004

/s/ Mariana R. Pfaelzer
Honorable Mariana R. Pfaelzer
United States District Judge

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Mar. 12, 2004]

Case No. CV 03-2567 MRP

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

JUDGMENT

THIS CONSTITUTES NOTICE OF ENTRY AS REQUIRED BY FRCP, RULE 77(d)

For reasons detailed in the Memorandum of Decision Re: Celltech's Motion for Entry of Final Judgment that was filed on February 18, 2004, this Court finds that it has fully considered and adjudicated the antitrust and unfair competition claims in this case. As there is no reason to delay appeal on those claims, this Court enters final judgment on the fifth, sixth, seventh, eighth, ninth and tenth causes of action. This Order is a final judgment for purposes of Fed.R. Civ.P. 54(a). It shall be entered pursuant to Fed.R.Civ.P. 58 and 79(a), and served upon the parties.

IT IS SO ORDERED

DATED: February 19, 2004

/s/ Mariana R. Pfaelzer
Honorable Mariana R. Pfaelzer
United States District Judge

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Mar. 17, 2004]

Case No. CV03-2567 MRP (CTx)
Hon. Mariana R. Pfaelzer

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

NOTICE OF APPEAL

Notice is hereby given that Plaintiff MedImmune, Inc. in the above named case hereby appeals to the United States Court of Appeals for the Federal Circuit from a Judgment, entered on March 15, 2004, dismissing MedImmune Inc.'s Fifth, Sixth, Seventh, Eighth, Ninth, and Tenth causes of action of its First Amended Complaint, (a copy of which is attached at Exhibit A).

Dated: March 17, 2004 DEWEY BALLANTINE LLP

By: /s/ Jeffrey R. Witham
JEFFREY R. WITHAM
Attorneys for Plaintiff
MEDIMMUNE, INC.

[Exhibit omitted in printing]

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Case No. CV 03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC.; CITY OF HOPE; and CELLTECH R&D LTD.,

Defendant.

GENENTECH'S NOTICE OF MOTION AND MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT

NOTICE OF MOTION AND MOTION

PLEASE TAKE NOTICE THAT at 10 a.m. on April 19, 2004, or as soon thereafter as the matter can be heard, before the Honorable Mariana R. Pfaelzer, in Courtroon 12 of the United States District Court for the Central District of California, Defendant Genentech, Inc. ("Genentech") will and hereby does move under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(3) for dismissal of all remaining causes of action, specifically: First Cause of Action (Declaratory Judgment on Contractual Rights and Obligatons), Second Cause of Action (Patent Invalidity), Third Casue of Action (Patent Unenforceability), and Fourth Cause of Action (Non-Infringement).

The motion against all remaining causes of action will be based on the grounds that this Court lacks subject matter jurisdiction over each of the claims and MedImmune lacks standing to bring these claims under the Declaratory Judgment Act.

This motion is based on this Notice of Motion and Motion, on the Memorandum of Points and Authorities filed concurrently herewith, on the pleading and papers on file in this action, and on the oral argument at the hearing on the motion. This motion is made following the conference of counsel pursuant to Local Rule 7-3 that took place on March 8, 2004.

Date: March 22, 2004

Respectfully submitted,
LATHAM & WATKINS LLP

By: /s/ Mark A. Flagel
MARK A. FLAGEL
Attorneys for Defendant
Genentech, Inc.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

Case No. CV-03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendant.

DEFENDANT CITY OF HOPE'S JOINDER IN DEFENDANT GENENTECH, INC.'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION

Defendant City of Hope hereby joins defendant Genentech, Inc.'s Motion to Dismiss for Lack of Subject Matter Jurisdiction. The Federal Circuit's decision in Gen-Probe v. Vysis, Inc., ___ F.3d ___, 2004 WL 405737, Case Nos. 02-1617, 02-1618 (Fed. Cir. Mar. 5, 2004) compels the conclusion that plaintiff MedImmune Inc.'s remaining claims must be dismissed for lack of subject matter jurisdiction.

City of Hope respectfully requests that this Court dismiss MedImmune's remaining claims against City of Hope, specifically: MedImmune's Second Cause of Action (seeking a declaration of Patent Invalidity), Third Cause of Action (seeking a declaration of Patent Unenforceability), and Fourth Cause of Action (seeking a declaration of Non-Infringement).

DATED: March 22, 2004

Respectfully submitted,

IRELL & MANELLA LLP
Morgan Chu
David I. Gindler
Joseph M. Lipner
Jason Linder

By: /s/ Jason Linder
JASON LINDER
Attorneys for Defendant
CITY OF HOPE

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Mar. 29, 2005]

Case No. CV03-2567 MRP (CTx)
Hon. Mariana R. Pfaelzer

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

DECLARATION OF DAVID M. MOTT IN SUPPORT OF PLAINTIFF MEDIMMUNE, INC.'S OPPOSITION TO GENENTECH, INC.'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION FILED UNDER SEAL

I, David M. Mott, hereby declare as follows:

1. I am the Chief Executive Officer of plaintiff MedImmune, Inc. ("MedImmune").

2. MedImmune is a Delaware corporation with its principal place of business in Gaithersburg, Maryland. MedImmune uses biotechnology to develop and produce antibody therapies.

3. MedImmune's most successful product, Synagis®, is used for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus ("RSV") in pediatric patients at high risk for RSV disease.

4. Research indicates that RSV infects approximately two-thirds of all infants during the first year of life and almost

100% of children by age two. It has also been found that RSV infection can be fatal in high-risk pediatric patients.

5. Synagis® was developed by MedImmune scientists during the early 1990's utilizing recombinant DNA technology.

6. Bringing this life-saving drug to market required a sustained effort spanning many years and costing many millions of dollars. After years of research and development, MedImmune conducted extensive clinical trials of Synagis® to prove to the FDA's satisfaction that this novel drug is not only safe, but also demonstrably effective in preventing RSV.

7. MedImmune obtained FDA approval to sell Synagis® in the U.S. in June of 1998. Synagis® was the first monoclonal antibody approved by the FDA to prevent an infectious disease.

8. MedImmune began selling Synagis® commercially in September 1998. Since then, Synagis® has become one of the most successful pediatric drugs ever marketed in the U.S.

9. Sales of Synagis® have accounted for over 80 percent of MedImmune's revenues from sales since 1999, including 82 percent in 1999; 86 percent in 2000; 89 percent in 2001; 85 percent in 2002; and 86 percent in 2003.

10. Synagis® remains MedImmune's most significant product to date and sales of Synagis® remain the driving force behind the company's revenue.

11. In or around December 2001, I was informed that Genentech, which at the time was one of the largest biotechnology companies in the United States, had been issued United States Patent No. 6,331,415 entitled "Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein" (the "Cabilly II Patent").

12. MedImmune had previously entered into a license agreement with Genentech in 1997 (the "1997 License

Agreement") to obtain certain rights to use Genentech's then-issued United States Patent No. 4,816,567 (the "Cabilly I Patent") and any related continuation or divisional applications, including the then pending application that matured into the Cabilly II Patent.

13. Despite the existence of the 1997 License Agreement, MedImmune has never paid Genentech any royalties under the Cabilly I Patent based on sales of Synagis®.

14. In or around January 2002, I was informed that Genentech had sent a letter dated January 7, 2002 demanding by March 1, 2002, payment of royalties for sales of Synagis® based on the Cabilly II Patent.

15. MedImmune considered Genentech's January 7th letter a clear threat to enforce the Cabilly II Patent against MedImmune. Genentech stated that it was writing "to confirm Genentech's expectation that MedImmune will pay royalties on sales of its Synagis® antibody product."

16. MedImmune disagreed with Genentech's position that royalties were due on March 1, 2002 because the Cabilly II Patent was invalid, unenforceable and/or not infringed by MedImmune's Synagis® product. Accordingly, our chief legal officer, Mr. William C. Bertrand, sent Genentech a letter dated February 13, 2002 asking for Genentech's basis for asserting that royalties were due.

17. Genentech did not provide MedImmune a written response by March 1, 2002, the date by which it had demanded that royalties be paid.

18. It was my understanding and belief, based on Genentech's letter and its public statements about the breadth and importance of the Cabilly II Patent, information within the industry, and practical business realities, that Genentech would terminate the 1997 License Agreement and sue MedImmune for patent infringement based on sales of Synagis® if MedImmune did not make the royalty payments as demanded.

19. Despite MedImmune's belief that the Cabilly II Patent was invalid, unenforceable and/or not infringed by MedImmune's Synagis® product, as Chief Executive Officer, I chose not to risk an immediate lawsuit by Genentech that could threaten sales of Synagis®, a life-saving drug, by the potential imposition of a preliminary or permanent injunction that would prevent MedImmune from selling the product.

20. Accordingly, MedImmune decided to pay royalties under protest (which MedImmune did after the March 1, 2002 deadline imposed by Genentech and the 1997 License Agreement) and subsequently challenge in court whether the Cabilly II Patent was valid, enforceable and/or infringed by MedImmune's Synagis® product.

21. After MedImmune made its first royalty payment, Genentech reasserted that the Cabilly II Patent was valid, enforceable and infringed by Synagis® in a letter dated March 24, 2002.

22. Genentech's January 7th and March 24th letters, along with its public statements, confirmed MedImmune's reasonable apprehension and the basic business reality that unless MedImmune continued to pay royalties before it obtains a court judgment that the Cabilly II Patent is invalid, unenforceable and/or not infringed by MedImmune's Synagis® product, Genentech would promptly terminate the 1997 License Agreement and file an infringement action against MedImmune.

23. This course of action, however, has not been without consequence for MedImmune, as it has paid . . . to Genentech on sales of Synagis® since March 4, 2002 on the Cabilly II Patent (a patent which it believes is invalid, unenforceable and/or not infringed by MedImmune's Synagis® product), including . . . paid during the pendency of this litigation.

I declare under penalty of perjury that the following is true and correct.

Dated: Gaithersburg, Maryland
March 29, 2004

/s/ David M. Mott
DAVID M. MOTT

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

Case No. CV03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

v.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

Hon. Mariana R. Pfaelzer

DECLARATION OF WILLIAM C. BERTRAND IN SUPPORT OF PLAINTIFF MEDIMMUNE, INC.'S OPPOSITION TO GENENTECH'S MOTION TO DISMISS FOR LACK OF SUBJECT MATTER JURISDICTION [FILED UNDER SEAL]

I, William C. Bertrand, hereby declare as follows:

1. I am the Vice President for Legal Affairs, General Counsel and Corporate Compliance Officer of plaintiff MedImmune, Inc. ("MedImmune").

2. I joined MedImmune on or about November 15, 2001.

3. In my capacity at MedImmune, I have responsibility for all legal matters, including all litigation, intellectual property and contractual matters. As part of that responsibility, I am generally familiar with the maintenance of records relating to MedImmune's negotiations with third parties with respect to intellectual property rights.

4. A true and correct copy of a letter from Clint Rogers of Genentech to Michael Richman of MedImmune dated June

11, 1997, enclosing a true and correct copy of an agreement between MedImmune and Genentech executed by MedImmune on or about June 2, 1997 (the "1997 License Agreement"), is attached hereto as Exhibit 1.

5. It is my understanding based on MedImmune's business records that, other than paying the initial $ . . . license grant fee, MedImmune did not make any royalty pay-ments on any sales of its Synagis® product under the 1997 License Agreement during the first four and a half calendar years the license was in effect.

6. A true and correct copy of a fascimile from Daryl Winter of Genentech to Mr. Richman dated November 4, 1999 is attached hereto as Exhibit 2. Among other things, this Genentech communication indicates that because the "'co-expression of immunoglobin [sic] chains in recombinant host cells' patent has not yet been issued to Genentech . . . no royalty is due under that application." It is my understanding that this is a reference to the application that issued as United States Patent No. 6,331,415 (the "Cabilly II Patent") on December 18, 2001.

7. A true and correct copy of a letter from Joseph E. Panigot of MedImmune to Mr. Winter dated November 5, 1999 is attached hereto as Exhibit 3.

8. A true and correct copy of a Genentech Press Release dated on or about December 18, 2001 is attached hereto as Exhibit 4.

9. A true and correct copy of a letter from Sean A. Johnston of Genentech to Mr. Richman dated January 7, 2002 is attached hereto as Exhibit 5. This letter references a telephone conversation between Messrs. Johnston and Richman and notes that "[f]urther to [such] telephone conversation . . ., I am writing to confirm Genentech's expectation that MedImmune will pay royalties on sales of its Synagis® antibody product pursuant to the license granted by Genen-

tech under the recently issued U.S. Patent No. 6,331,415." The letter demanded that the royalties be paid "on or before March 1, 2002."

10. A true and correct copy of my letter to Mr. Johnston dated February 13, 2002 is attached hereto as Exhibit 6.

11. A true and correct copy of an article published in Nature Biotechnology dated February, 2002 is attached hereto as Exhibit 7.

12. Genentech did not respond to my February 13th letter by March 1, 2002, the date it demanded that the royalties be paid.

13. Based on, among other things, Mr. Johnston's January 7th letter, Genentech's refusal to respond to my February 13th letter by the date the royalty demand was due, Mr. Johnston's and Genentech's public statements about the breadth of the Cabilly II Patent, and obvious business realities, including, among other things, the dominant position of Genentech in the biotechnology industry (i.e., at that time it is my understanding that Genentech was one of the largest biotechnology companies in the United States) and the large amount of sales of MedImmune's Synagis® product, it was clear that Genentech would consider a failure by MedImmune to make royalty payments a material breach of the 1997 License Agreement, which would allow Genentech to terminate the agreement and sue MedImmune for patent infringement thereafter. MedImmune could do nothing to prevent Genentech from taking these actions, and it would have been logical for Genentech to do so.

14. A true and correct copy of my letter to Mr. Johnston dated March 8, 2002 is attached hereto as Exhibit 8.

15. A true and correct copy of Mr. Johnston's letter to me dated March 24, 2002 is attached hereto as Exhibit 9.

16. A true and correct copy of my letter to Mr. Johnston dated April 4, 2002 is attached hereto as Exhibit 10.

17. A true and correct copy of Mr. Johnston's letter to me dated May 16, 2002 is attached hereto as Exhibit 11.

18. A true and correct copy of my letter to Mr. Johnston dated May 23, 2002 is attached hereto as Exhibit 12.

* * *

I declare under penalty of perjury that the following is true and correct.

Dated: Gaithersburg, Maryland
March 29, 2004

/s/ William C. Bertrand
WILLIAM C. BERTRAND

[*Exhibit 1 to Bertrand Declaration*]

Genentech, Inc.

June 11, 1997

Sent by Federal Express

Michael Richman
Vice-President, Business Development
MedImmune, Inc.
35 West Watkins Mill Road
Gaithersburg, MD 20878

Dear Mike:

Enclosed please find a fully executed agreement between MedImmune and Genentech which grants a license to MedImmune under Genentech's Cabilly patents for antibodies binding the respiratory syncytial virus antigen.

As we discussed and agreed to, I would like to confirm that the royalty paid by MedImmune to the Medical Research Council for licenses to the Winter and Boss patents applies to Section 3.05(b) of the enclosed agreement regarding "Credits Against Royalties."

The license grant fee of $ . . . should be paid to Genentech within thirty days of your receipt of this agreement. Payment should be made by wire transfer according to the enclosed directions.

I would like to express my sincere appreciation for your efforts in completing this agreement, and I wish MedImmune the best in its development of antibodies to RSV.

With best regards,

/s/ Clint Rogers

CLINT ROGERS
Senior Analyst
Business and Corporate Development

Direct Telephone: (415) 225-6021
Direct Facsimile: (415) 225-3009
E-mail: *rogers.clint@gene.com*

GENENTECH, INC.

MAILING ADDRESS:

Genentech, Inc.
Treasury Department (Mail Stop 24)
460 Point San Bruno Boulevard
South San Francisco, CA 94080

FAX NUMBER:

(415) 225-2848

WIRE INSTRUCTIONS:

Bank:	Citibank, N.A.
Address:	399 Park Avenue New York, NY 10043
ABA Number:	021-000-089
Account Name:	Genentech, Inc.
Account Number:	4052-7763

TAX I.D. NUMBER

94-2347624

This Agreement, dated as of June 4, 1997 is between Genentech, Inc., a Delaware corporation having a principal place of business at 460 Point San Bruno Blvd., South San Francisco, California 94080 (hereinafter "Genentech") and MedImmune, Inc. having a place of business at 35 West Watkins Road, Gaithersburg, Maryland 20878 (hereinafter "Licensee")

WHEREAS:

A. Genentech is the owner of certain patents and patent applications (patent rights) relating to methods and compositions in the field of immunoglobulins.

B. Genentech does not wish to have these patent rights hinder the development of immunoglobulin products and is willing to grant licenses for the development of products for public use and benefit as specified in this Agreement.

C. Licensee desires to obtain a license under the terms and conditions specified herein.

D. Genentech and Licensee believe that the subject matter of this license will be most effectively commercialized under conditions of limited exclusivity to encourage the investments required to develop and market such subject matter.

NOW, THEREFORE, the parties agree as follows:

Article I

DEFINITIONS

Unless otherwise specifically set forth herein, the following terms shall have the following meanings:

1.01. "Affiliate" of Licensee shall mean any entity that controls, is controlled by or is under common control with Licensee; and "control" for purposes of this definition shall mean the possession of the power to direct or cause the direc-

tion of the management and policies of an entity, whether through the ownership of voting stock, by contract or otherwise. In the case of a corporation, "control" shall mean the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting stock together with a controlling membership on the board of directors of such corporation.

1.02. "Antigen" as used in this Agreement shall mean the respiratory syncytial virus (RSV) substance listed in Schedule A attached hereto and made a part of this Agreement. Schedule A may be amended from time to time by mutual agreement of the Parties in writing, at which time the financial terms pertaining to the newly added Antigen(s) may also be modified.

1.03. "Bulk Product" shall mean Licensed Product supplied in a form other than Finished Product which can be converted into Finished Product.

1.04. "Cost of Product" shall mean the cost of acquisition, if purchased, or the cost of manufacture, the latter being the sum of direct production costs and manufacturing overhead costs determined in accordance with generally accepted accounting principles.

1.05. "Designee" shall mean a person or entity designated by a Party to exercise the rights of and perform obligations hereunder in place of and to the exclusion of that Party in the Territory or a portion thereof.

1.06. "Effective Date" shall mean as to each Antigen, or Licensed Product based thereon, the later of the date of this Agreement or the date on which such Antigen was added to Schedule A by amendment.

1.07. "Field" shall mean the manufacture, use or sale of Licensed Product for the prevention or therapy of human diseases.

1.08. "Finished Product" shall mean any and all Licensed Products in form for use by an end user and not intended for further chemical or genetic manipulation or transformation.

1.09. "Licensed Patents" shall mean

(a) U.S. Patent No. 4,816,567 and the claims relating to chimeric antibodies found in patents or patent applications arising from divisionals, continuations or continuations-in-part of any application from which U.S. Patent No. 4,816,567 claims priority (excluding U.S.S.N. 07/205,419 and foreign counterparts thereof) as well as the foreign counterparts of the foregoing and any and all reissues, reexaminations or extensions of the foregoing ("Chimera Patents") and

(b) any patent issuing based on U.S.S.N. 07/205,419 (a continuation of the application maturing into U.S. Patent No. 4,816,567) relating to the coexpression of immunoglobulin chains in recombinant host cells, as well as the divisionals, continuations or continuations-in-part of such U.S.S.N. 07/205,419, the issued foreign counterparts of such U.S.S.N. 07/205,419 and any and all reissues, reexaminations or extensions of the foregoing ("Coexpression Patents"). Attached hereto as Schedule B is a list of patents and patent applications that Genentech in good faith believes represents Licensed Patents as of September 1, 1996. However no warranty is given as to the completeness or accuracy of Schedule B or any update thereof that might subsequently be provided to Licensee.

1.10. "Licensed Product(s)" shall mean the anti-RSV monoclonal antibody capable of binding to the Antigen listed in Schedule A hereto, the manufacture, use or sale of which substances would, if not licensed under this Agreement, infringe one or more claims of either or both of Chimera Patents or Coexpression Patents, which have neither expired nor been held invalid by a court or other body of competent jurisdiction from which no appeal has been or may be taken.

1.11. . . . .

1.12. "Party" shall mean Genentech or Licensee and when used in the plural shall mean Genentech and Licensee.

1.13. "Territory" shall mean the entire world.

Article II

GRANT

2.01. *License*. Subject to the fulfillment by Licensee of all the terms and conditions of this Agreement, Genentech hereby grants to Licensee and Licensee hereby accepts a coexclusive license together with the right to sublicense its Affiliates and Designees under Licensed Patents for the term thereof to make, use and sell Licensed Products in the Field and the Territory. This grant shall be coexclusive with Genentech, Inc., and additional licensees, if any, to be selected solely by Genentech. Genentech shall be free at its discretion to enter into agreements with such additional licensees at any time and on terms solely of its choosing. However, Genentech represents that, unless for a particular Antigen a different number of additional licenses is specified at the time such Antigen is included in Schedule A, it will not grant more than four (4) additional licenses in which both the Field and Territory are coextensive with that which is set forth herein.

2.02. *Right to Appoint Designee*. Licensee shall have the right to sublicense all of its rights hereunder for all or part of the Territory (including on a country-by-country basis) to a Designee of its choosing, to the exclusion of Licensee in such Territory or portion thereof, provided that Licensee agrees that it will indemnify Genentech for any failure of performance on the part of such Designee. An entity that simply acts to co-promote or to co-market Licensed Product supplied by Licensee shall not be considered a Designee and Licensee may co-promote or co-market such Licensed Product with such entity in a given country or countries, provided that (i) both Licensee and such entity obtain Licensed Products from the same manufacturing source, (ii) only one such entity shall be permitted to co-promote or co-market the same Licensed Product in a given country, and (iii) Licensee shall be responsible for the payment of royalties on Net Sales of

Licensed Products by such entity and for all other acts of such entity as if such acts were those of the Licensee.

2.03. *No Other License.* Licensee understands and agrees that no license under any patent or application other than Licensed Patents is or shall be deemed to have been granted under this Agreement, either expressly or by implication.

2.04. *Licenses Separately Available.* Licensee acknowledges that separate licenses under Chimera Patents and Coexpression Patents were available from Genentech upon request prior to entering into this Agreement, but that for reasons of convenience the licenses have been combined in this Agreement. Licensee further acknowledges that it was not coerced to enter into a license under either one of Chimera or Coexpression Patents as a condition to obtaining a license under the other, and that the licenses hereunder were not offered as a mandatory package.

Article III

FEES AND ROYALTIES

3.01. *License Grant Fee.* Within thirty (30) days after execution of this Agreement or amendment of Schedule A to add an Antigen thereto, Licensee shall pay to Genentech a non-creditable, non-refundable license grant fee of $ . . . per Antigen.

3.02. *Minimum Annual Royalties.* Licensee shall pay to Genentech a minimum annual royalty for each Antigen on or before January 31 of each year beginning with the third full

calendar year after the Effective Date for such Antigen in accordance with the following table:

Full Calendar Year	*Minimum Annual Royalty*
3	$ . . .
4	$ . . .
5	$ . . .
6 and each subsequent year	$ . . .

Such payments shall be non-refundable but shall be creditable against earned royalties as provided in Section 3.05.

3.03. *Earned Royalties*. . . . .

3.04. *Sales To and Between Sublicensees*. . . . .

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3.05. *Credits Against Royalties*. . . . .

3.06. *No Non-Monetary Consideration.* . . . .

3.07. *Most Favored Licensee.* . . . .

Article IV

RECORDS, REPORTS AND PAYMENTS

4.01. *Records Retention.* Licensee shall keep and shall cause its sublicensees to keep records of the sales of all Licensed Products in sufficient detail to permit Genentech to confirm the accuracy of Licensee's royalty calculations. At Genentech's request and expense, Licensee shall permit an independent certified public accountant appointed by Genentech and acceptable to Licensee to examine upon reasonable notice and at reasonable times, such records solely to the extent necessary to verify Licensee's calculations. Such examination shall be limited to a period of time no more than three (3) years immediately preceding the request for examination. If Licensee's royalties are found to be in error such that royalties to Genentech were underpaid by more than five (5) percent then Licensee shall promptly pay any deficiency, plus interest at the prime rate, to Genentech and reimburse Genentech for its costs in examining such records.

4.02. *Reports*. Within sixty (60) days after the end of each calendar quarter following Licensee's or its sublicensee's first sale of Licensed Product, Licensee shall furnish to Genentech a written report of all sales of Licensed Products subject to royalty under Section 3.03 during such calendar quarter. Such report shall include (i) the determination of Net Sales as specified in Section 1.11; (ii) detailed itemization of the credits taken pursuant to Section 3.05; and (iii) the royalty payment then due.

4.03. *Payments*. Concurrently with each report pursuant to Section 4.02, Licensee shall make the royalty payment then due. Payments shall be in United States dollars and, unless otherwise agreed in writing, shall be made by wire transfer to such bank as Genentech may from time to time designate in writing, without set-off and free and clear of and without any deduction or withholding for or on account of any taxes, duties, levies, imposts, fees or charges except .for withholding required by tax authorities for income taxes on royalties actually payable to Genentech after application of the credits permitted by Sections 3.05. Licensee shall make any withholding payments due on behalf of Genentech and shall promptly provide Genentech with official tax receipts or other written documentation sufficient to enable Genentech to satisfy the United States tax authorities with respect to Genentech's application for a foreign tax credit for such payment.

4.04. *Currency Conversion*. Royalties due on Net Sales of Licensed Products made in currency other than United States dollars shall first be calculated in the foreign currency and then converted to United States dollars on the basis of the rate of exchange in effect for purchase of dollars published in the *Wall Street Journal* on the last business day of the period for which royalties are due.

Article V

LIABILITY

5.01. *Indemnification.* Licensee shall defend, indemnify and hold Genentech harmless against any and all liability, damage, loss, cost or expense resulting from any third party claim, suit or other action arising out of or based on the manufacture, use or sale of any Licensed Product by Licensee, its sublicensees or co-promoting or co-marketing entities pursuant to Section 2.02: provided, however, that upon the filing of any such claim or suit, Genentech shall promptly notify Licensee and permit Licensee, at Licensee's cost, to handle and control such claim or suit and shall cooperate in the defense thereof.

Article VI

PATENT INFRINGEMENT

6.01. *Notification of Infringement.* Licensee shall notify Genentech of any infringement by third parties of any patent within Licensed Patents of which Licensee is aware and shall provide Genentech with the available evidence, if any, of such infringement.

6.02. *Enforcement of Licensed Patents.* . . . .

6.03. *No Warranty of Non-Infringement.* Nothing in this Agreement shall be construed as a representation made or warranty given by Genentech that the practice by Licensee or its sublicensees of the license granted hereunder will not infringe the patent rights of any third party.

Article VII

TERM AND TERMINATION

7.01. *Term.* This Agreement shall come into force as of its Effective Date and shall continue in full force and effect on a country-by-country basis unless earlier terminated as pro-

vided herein or until the expiration of the last to expire of the Licensed Patents.

7.02. *Termination for Breach.* Genentech shall have the right to terminate this Agreement and the licenses granted hereunder upon thirty (30) days' written notice to Licensee for Licensee's material breach of this Agreement if Licensee has failed to cure such breach within thirty (30) days of notice thereof.

7.03. *Insolvency.* Either Party may terminate this Agreement if, at any time, the other Party shall file in any court pursuant to any statute of any individual state or country, a petition in bankruptcy, insolvency or for reorganization or for an agreement among creditors or for the appointment of a receiver or trustee of the Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party shall be served with an involuntary petition against it filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if the other Party shall propose or be a Party to any dissolution or liquidation, or if the other Party shall make an assignment for the benefit of creditors.

7.04. *Termination by Licensee.* Licensee may terminate this Agreement in its entirety or with respect to one or more Antigens at any time upon six (6) months' written notice to Genentech.

7.05. *Effect of Termination.* Termination of this Agreement in whole or in part for any reason shall not relieve Licensee of its obligations to pay all fees and royalties that shall have accrued hereunder prior to the effective date of termination. Termination of this Agreement as to Licensee shall result in the termination of the licenses of Licensee and all sublicensees of Licensee. The provisions of Sections 2.04 and 3.08 shall survive termination of the Agreement for any reason except termination for breach by Genentech.

Article VIII

MISCELLANEOUS PROVISIONS

8.01. *Limitations on Assignments.* Neither this Agreement nor any interests hereunder shall be assignable by either Party without the written consent of the other; provided, however, that either Party may assign this Agreement to any corporation or entity with which it may merge or consolidate, or to which it may transfer substantially all of its assets or all of its assets to which this Agreement relates without obtaining the consent of the other Party.

8.02. *Jurisdiction and Choice of Laws.* This Agreement shall be interpreted and construed under the laws of California, and Licensee agrees to submit to the jurisdiction of California.

8.03. *Relationship of the Parties.* Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, employer-employee, or joint venture relationship between the Parties.

8.04. *Further Acts and Instruments.* Each Party hereto agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate to effect the purpose and intent of this Agreement.

8.05. *Entire Agreement.* This Agreement constitutes and contains the entire agreement of the Parties and supersedes any and all prior negotiations, correspondence, understandings and agreements between the Parties respecting the subject matter hereof. This Agreement may be amended or modified or one or more provisions thereof waived only by a written instrument signed by the Parties.

8.06. *Severability.* If in any jurisdiction any one or more of the provisions of this Agreement should for any reason be held by any court or authority having jurisdiction over this Agreement or any of the Parties hereto to be invalid, illegal or

unenforceable, such provision or provisions shall be validly reformed to as nearly approximate the intent of the Parties as possible and if unreformable, the Parties shall meet to discuss what steps should be taken to remedy the situation; in other jurisdictions, this Agreement shall not be affected.

8.07. *Captions*. The captions to this Agreement are for convenience only and are to be of no force or effect in construing and interpreting the provisions of this Agreement.

8.08. *WARRANTIES*. The Parties represent and warrant that they have the power to enter into this agreement. OTHERWISE, THE PARTIES EXPRESSLY DISCLAIM ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT.

8.09. *Notices*. Any notice, request, approval or other document required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given when delivered in person, transmitted by telex, telecopier, telegraph or deposited in the mail, postage prepaid, for mailing by first class, certified or registered mail, return receipt requested, addressed as follows:

If to Licensee, addressed to:

MedImmune, Inc.
35 West Watkins Mill Road
Gaithersburg, MD 20878
Attn.: Chief Executive Officer

If to Genentech, addressed to:

Genentech, Inc.
460 Point San Bruno Boulevard
South San Francisco, CA 94080
Attn: Corporate Secretary

or to such other address or addresses as may be specified from time to time in a written notice.

8.10. *Wire Transfer of Funds.* Unless otherwise specified in writing, all payments by Licensee required hereunder shall be made by wire transfer at the direction of Genentech.

IN WITNESS WHEREOF, Genentech and Licensee have caused this Agreement to be executed by their duly authorized representatives.

MEDIMMUNE, INC.

By: /s/ David M. Mott

Title: President & C.O.O.

Date: 6/2/97

GENENTECH, INC.

By: /s/ [illegible]

Title: Vice President

Date: 6/5/97

Schedule A

Antigens

[Redaction]

SCHEDULE B

Patents and Patent Applications

[Redaction]

[*Exhibit 2 to Bertrand Declaration*]

GENENTECH, INC.
BUSINESS AND CORPORATE DEVELOPMENT

FACSIMILE TRANSMITTAL SHEET

TO	FROM
Michael Richman	Daryl Winter
COMPANY.	DATE
MedImmune, Inc.	11/04/99
RE	TOTAL NO OF PAGES INCLUDING COVER
Cabilly License	1
PHONE NUMBER	PHONE NUMBER
301-527-4454	650-225-1249
FAX NUMBER	FAX NUMBER
301-527-4201	650-225-3009

Dear Michael:

Based on our recent discussions, it is my understanding that MedImmune does not intend to take a Cabilly license for MEDI-507 (anti-CD2) at this time. Please keep in mind that the availability of a license for a particular antigen depends, among other things, on the demand by other companies for license to that antigen, and as such, we can not guarantee that licenses will be available in the future. . . . .

On a separate but related matter, I have reviewed our license with MedImmune dated June 4, 1997. According to our Finance department, no quarterly payments or reports have been submitted regarding payment of Royalties on New Sales of Synagis, anti RSV, since this product has been marketed.

While the "co-expression of immunoglobin chains in recombinant host cells" patent has not yet been issued to Genentech, and thus under § 1.10, no royalty is due under that application, U.S. Patent 4,815,567 related to chimeric antibodies is in force and accordingly we believe. . . . .

Please advise us of the reasons for the absence of quarterly reports and royalty payments. Your prompt response to this inquiry would be most appreciated.

Should you have any questions on either of the issues mentioned above, please do not hesitate to contact me.

Regards,

/s/ Daryl Winter

[*Exhibit 3 to Bertrand Declaration*]

[Logo]

MedImmune, Inc.

November 5, 1999

Daryl Winter
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080

Dear Mr. Winter:

In response to the communication you faxed earlier today, I would like to take the opportunity to ensure that our intent in obtaining a license for the Cabilly patent is not misunderstood. Although I had previously expressed concerns regarding the financial terms being offered, we are still nonetheless interested in licensing this patent. I will contact you subsequently to discuss this further.

I would also like to respond to your analysis of MedImmune's royalty obligation concerning US Patent 4,816,567 (the '567 Patent). MedImmune has consistently maintained that due to its humanized nature, Synagis® falls outside the claims of chimeric antibody patents. Thus, we do not believe that there is a royalty obligation to Genentech based upon the '567 patent.

I hope these explanations are helpful. If you have any questions or concerns regarding these matters, please do not hesitate to contact me.

Sincerely,

/s/ Joseph E. Panigot
JOSEPH E. PANIGOT
Associate director, Business Development

cc: Michael Richman

[*Exhibit 4 to Bertrand Declaration*]

Genentech, Inc.

[Logo]

NEWS
PRESS RELEASE

Genentech Granted Fundamental U.S.
Patent for Antibody Technology

SOUTH SAN FRANCISCO, Calif.—December 18, 2001—Genentech, Inc. (NYSE: DNA) announced that the United States Patent and Trademark Office today granted U.S. Patent No. 6,331,415 relating to fundamental methods and compositions used to produce antibodies by recombinant DNA technology.

This patent, which has clams for the co-expression of antibody heavy and light chains, covers a principal way that therapeutic and diagnostic antibodies are made by biotechnology and pharmaceutical companies and others using recombinant DNA technology. Examples of such antibodies at Genentech include the Herceptin® antibody product for the treatment of certain forms of HER-2 overexpressing metastatic breast cancer, and the Rituxan® antibody product for the treatment of certain forms of B-cell non-Hodgkin's lymphoma. Genentech has a number of existing licensing agreements in place that grant rights under this patent to other companies for certain other antibodies developed by those companies. Genentech expects that a number of additional companies will seek licenses under the patent.

The patent is based on a collaboration between scientists at Genentech and at the City of Hope National Medical Center in the early 1980s, and it is the second U.S. Patent to result from that collaboration. The patent is unrelated to recent contract disputes between Genentech and the City of Hope. The patent granted today follows almost ten years of

proceedings in the Patent Office and in the United States District Court to determine whether the invention covered by the patent was invented first by scientists at Genentech and City of Hope or by scientists at Celltech in England. Earlier this year, following a court-ordered mediation that resulted in an agreement between Genentech and Celltech to settle the priority dispute, the court determined that Genentech was entitled as a matter of law to priority over Celltech and accordingly, that Genentech should be awarded the patent on the invention. Following that determination, the Patent Office again independently examined Genentech's patent application and concluded that the patent should issue.

Genentech, Inc. is a leading biotechnology company that discovers, develops, manufactures and markets human pharmaceuticals for significant unmet medical needs. Fifteen of the currently approved biotechnology products stem from or are based on Genentech science. Genentech markets ten biotechnology products directly in the United States. The company has headquarters in South San Francisco, Calif. and is traded on the New York Stock Exchange under the symbol DNA.

[*Exhibit 5 to Bertrand Declaration*]

Genentech, Inc.

LEGAL DEPARTMENT
1 DNA Way
South San Francisco, CA 91080-4990
(650) 225-1000
FAX (650) 952-9881 or (650) 952-9882

January 7, 2002

VIA FEDERAL EXPRESS
Michael S. Richman
Senior Vice-President, Corporate Development
and Administration
MedImmune, Inc.
35 West Watkins Mill Road
Gaithersburg, MD 20878

Dear Mike:

Further to our telephone conversation a couple of weeks ago, I am writing to confirm Genentech's expectation that MedImmune will pay royalties on sales of its Synagis® antibody product pursuant to the license granted by Genentech under the recently issued U.S. Patent No. 6,331,415.

According to the license Agreement between our companies dated June 4, 1997, the royalty owed for the license under the '415 patent is. . . . . Royalty payments are due on a quarterly basis, within sixty days following the end of each calendar quarter. Because the '415 patent issued on December 18, 2001 the first royalty payment will be due on or before March 1, 2002.

Should you have any questions regarding this matter, please do not hesitate to contact me.

Very truly yours,
GENENTECH, INC.

/s/ Sean Johnston
SEAN A. JOHNSTON
Vice President, Intellectual Property

[*Exhibit 6 to Bertrand Declaration*]

[Logo]

MedImmune, Inc.

February 13, 2002

BY TELECOPIER

Sean A. Johnston, Esq.
Vice President, Intellectual Property
Genentech, Inc.
Legal Department
1 DNA Way
South San Francisco, CA 94080-4990

Dear Sean:

This is in response to your January 7, 2002 letter to Michael Richman regarding Genentech's U.S. Patent No. 6,331,415 (the "'415 Patent").

While we understand that Genentech has an "expectation that MedImmune will pay royalties on sales of Its Synagisa® antibody product pursuant to the license [Agreement dated June 4, 1997 (the "Agreement")]," it would be helpful if you could please advise us as to your basis for believing that MedImmune's product would infringe any valid claim of the '415 Patent such that royalties would be due.

In addition, we would appreciate it if you could give us a copy of the settlement agreement entered into between Genentech and Celltech R&D, Inc. which resulted in the issuance of the '415 Patent (and the revocation of the Boss patent, to which MedImmune has a license), the interference file itself, as well as the documentary evidence that was cited by the U.S. District Court for the Northern District of California as the reason for the settlement agreement giving the '415 Patent priority over the now-revoked Boss patent.

Finally, as you know, the Agreement is now drafted to cover products binding to antigens listed in Schedule A, which currently include "[a]ntigens expressed by respiratory syncytial virus . . . ." We have previously inquired about the possibility of adding additional antigens to Schedule A (as contemplated by Section 1.02 of the Agreement) and you advised us that Genentech had not, as of that time, reached a decision on this matter and on its licensing policy with respect to the '415 Patent generally. We trust that by now Genentech has determined its position and we would appreciate your advising us of it. In particular, without conceding that such a license would be required, we are interested in knowing whether Genentech is willing to provide MedImmune with a license under the '415 Patent for the following MedImmune products under development: (1) Medi-507 (anti-CD2 antibody); (2) Vitaxin (TM) (anti $\alpha_1\beta_3$ antibody); (3) antibodies against IL-9 (or IL-9 receptor) and (4) antibodies against EphA2.

Thank you in advance for your help and cooperation.

Very truly yours,

/s/ William C. Bertrand, Jr.
WILLIAM C. BERTRAND, JR.
Vice President, Legal Affairs

[*Exhibit 7 to Bertrand Declaration*]

Nature Biotechnology, February 2002, p. 108

Genentech awarded critical antibody patent

In December 2001, after a more than decade-long dispute over inventorship with Celltech R&D Ltd (Slough, UK), the biotech giant Genentech (S. San Francisco, CA) was awarded a patent claiming broad rights to fundamental methods for the recombinant expression of antibodies. The patent covers one of the principal processes used in the manufacturing of lucrative therapeutic and diagnostic antibody drugs, such as Genentech's breast-cancer therapeutic Herceptin, and could potentially block the production of antibody products by rival companies or increase their royalty burden.

Genentech's US Patent No. 6,331,415 ("Cabilly patent"), which was awarded on December 18, is a continuation of a previously issued Cabilly patent filed by Genentech on April 8, 1983 as part of a collaborative effort between Genentech and the City of Hope National Medical Center (Duarte, CA). The newly issued patent has 36 claims for recombinant methods and vectors to produce immunoglobulin (Ig) molecules and functionally Ig fragments in transformed host cells.

Genentech's application was on file with the US Patent and Trademark Office (PTO; Washington DC) when Celltech's US patent 4,816,397 ("Boss patent"), covering the same patentable invention, was granted in March 1989, having been filed on March 24, 1983. In February 1991, after the issuance of the Boss patent, Genentech asked the Board of Patent Appeals and Interferences to begin an interference action to determine which of the two companies had rights to the invention.

Seven years later in August 1998, a panel of administrative patent judges found in favor of Celltech, criticizing the evidentiary value of the Genentech inventor's notebooks and corroborating evidence. Genentech responded by filing suit

A court-ordered settlement—required by the US District Court before it would render its decision on inventorship—provides Celltech with a license to the Genentech patent to continue its R&D activities in return for an undisclosed royalty on future product sales. Notably, Genentech will pay Celltech for any lost income it would have generated from increasing revenue or the sales of any products covered by the Boss patent, which would have expired in 2006.

Meanwhile, Genentech believes that issuance of the Cabilly patents could affect many companies. "The recently issued patent broadly covers the co-expression of immunoglobulin heavy and light chain genes in a single host cell," says Sean Johnston, Genentech's vice president of intellectual property. "We do not believe that the claims are limited by type of antibody (murine humanized [90% human sequence], or human) or by host cell type."

Leading antibody companies, such as IDEC (San Diego, CA), Abgenix (Freemont, CA), and Medarex (Princeton, NJ) are now comparing their technologies with the issued patent claims to determine whether they need a license from, or should pay royalties on current products to, Genentech. And Celltech licensees—such as ImClone Systems (New York), which is co-developing an anti-cancer drug with Bristol

Myers Squibb—may now need to go to Genentech for a license. Some suggest that if licensing and royalty payments are owed, there will be corresponding increase in the production costs of those therapeutic and diagnostic antibodies. But Genentech disagrees. "Any increased cost depends largely on the particular antibody, the technology used to produce the antibody, and how many of those steps need to be licensed," says Johnston.

Investors are also scrambling to determine whether companies will now need to pay unanticipated royalties. "This patent aroused our interest because there are 11 antibody-based drugs on the market and over 90 additional products under development at various biotechnology companies," says BancAmerica Securities (New York) biotechnology analyst Thomas McGahren. "We have reviewed this patent and consider it to be very important, and companies producing chimeric or humanized antibodies will have to review carefully and determine if they need a license," says McGahren. "From an investment perspective, we are interested whether companies, such as MedImmune, will need a license or pay royalties on this essentially basic genetic engineering technology because they produce humanized antibodies," he adds. "Medarex and Abgenics, which produce human antibodies, may not have to face additional royalty and licensing feet."

Debra Robertson, San Diego, CA

[*Exhibit 8 to Bertrand Declaration*]

[Logo]

MedImmune, Inc.

March 8, 2002

BY TELECOPIER

Sean A. Johnston, Esq.
Vice President, Intellectual Property
Genentech, Inc.
Legal Department
1 DNA Way
South San Francisco, CA 94080-4990

Dear Sean:

This is a follow-up to our letter of February 13, 2002, which responded to your January 7, 2002 letter to Michael Richman regarding Genentech's U.S. Patent No. 6,331,415 B1 (the "'415 Patent").

To date, we have not yet received any response to the questions we asked in our February 13th letter. As we then indicated, we require responses to our inquiries and the documents we requested in order to evaluate your claim that MedImmune owes royalties to you pursuant to our June 4, 1997 agreement. As you know we wired you a payment on March 4, 2002 in the amount of $ . . . . Such payment, however, was made under protest and with reservation of all of our rights. We expect an answer to our questions immediately so that we may evaluate how further to proceed.

Very truly yours,

/s/ William C. Bertrand, Jr.
WILLIAM C. BERTRAND, JR.
Vice President, Legal Affairs

[*Exhibit 9 to Bertrand Declaration*]

Genentech, Inc.

LEGAL DEPARTMENT
1 DNA Way
South San Francisco, CA 94080-4990
(650) 225-1000
FAX (650) 952-9881 or (650) 952-9882

March 24, 2002

VIA FACSIMILE (301)527-4214
William C. Bertrand, Jr.. Esq.
Vice President, Legal Affairs
MedImmune, Inc.
35 West Watkins Mill Road
Gaithersburg, MD 20878

Re: Agreement between Genentech and MedImmune dated June 4, 1997

Dear Bill:

I am writing in response to your letter to me dated February 13, 2002, regarding Genentech's U.S. Patent No. 6,331,415, under which MedImmune currently has a license to make, use, and sell its Synagis® humanized monoclonal antibody product.

The United States Patent and Trademark Office ("PTO") issued the '415 patent to Genentech after litigation in the United States District Court to resolve the issue of whether Genentech or Celltech Therapeutics had priority to the claimed invention. The District Court issued findings of fact and conclusions of law that Genentech had, as a matter of law, established and was entitled to priority. After the District Court issued those findings and conclusions, Genentech filed with the PTO voluminous documents including (a) all pleadings filed in the District Court action, (b) transcripts of all depositions, including exhibits, taken in the District Court

action, (c) all documents produced in the District Court action, and (d) Genentech's settlement agreement with Celltech. The PTO thereafter independently examined Genentech's pending application and concluded that it met all of the requirements of patentability under the United States Code. The PTO also cancelled the claims of Celltech's U.S. Patent No. 4,816,397.

Your letter asks for the basis of Genentech's belief that MedImmune's Synagis product is within the scope of the claims of the '415 patent. Our belief is based primarily on our understanding that Synagis is an immunoglobulin molecule composed of heavy and light claims (each chain including a variable domain) that is produced by a process that involves the use of certain recombinant DNA technology to co-express the heavy and light chains in a single host cell. If our understanding is incorrect, please let us know in what respect it is incorrect, and what the correct information is regarding the structure of Synagis and/or the process by which it is produced, so that we may reevaluate our position.

Your letter states that "it would be helpful" to know the basis of Genentech's belief that is MedImmune's Synagis product is within the scope of the claims of the '415 patent. Obviously, however, MedImmune is able to evaluate for itself whether it believes the Synagis product is within the scope of the claims of the '415 patent. In this regard, we note with appreciation MedImmune's March 4, 2002 royalty payment, under the '415 patent, on sales of Synagis.

Your letter also asks for numerous documents, including the settlement agreement between Genentech and Celltech. The settlement agreement is a confidential document, and we cannot provide it to you. The documents you have requested are amongst those that Genentech filed with the PTO before the '415 patent issued, and, as noted above, both the District Court and the PTO concluded based on all the evidence that Genentech was entitled to the '415 patent. We do not believe

that the documents you have requested are relevant to the question of whether or why MedImmune must pay Genentech further royalties. Nevertheless, if there are a few specific documents from the prosecution of the '415 patent, the interference proceeding in the PTO, or from the litigation in the District Court that you would like to review, please let us know which ones those are and we will try to provide copies of them to you from our own files. Because the complete set of such documents is voluminous, if you wish to review more than just a few, you should obtain copies of the documents directly from the PTO, as allowed by law.

Finally, your letter asks whether, and under what terms, Genentech would be willing to grant MedImmune a license under the '415 patent for various antibody products that MedImmune has under development. We appreciate MedImmune's interest in additional licenses under the '415 patent, and hope to be able to respond to you shortly. We look forward to continuing our commercial relationship.

Very truly yours,

GENENTECH, INC.

/s/ Sean Johnston
SEAN A. JOHNSTON
Vice President, Intellectual Property

[*Exhibit 10 to Bertrand Declaration*]

[Logo]

MedImmune, Inc.
April 4, 2002

VIA FACSIMILE

Sean A. Johnston, Esq.
Vice President, Intellectual Properly
Legal Department
Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080-1990

Re: Genentech's U.S. Patent No. 6,331,415 ("'415 Patent")

Dear Sean:

We have your letter dated March 24, 2002 relating to the '415 Patent.

We are disappointed by your refusal to provide us with a copy of the settlement agreement entered into between Genentech and Celltech R&D, Inc. which resulted in the issuance of the '415 Patent as well as the documentary evidence that was cited by the U.S. District Court for the Northern District of California as the reason for the settlement agreement giving the '415 Patent priority over the now-revoked Boss patent.

Your letter states that after the District Court order announcing the settlement, "Genentech filed with the PTO voluminous documents including (a) all pleadings filed in the District Court action, (b) transcripts of all depositions, including exhibits, taken in the District Court action, (c) all documents produced in the District Court action, and (d) Genentech's settlement agreement with Celltech." However, there is no reference to any of these materials in the docket sheets for either the Interference file or the '415 Patent prosecution file.

If you would tell us where and when these materials were filed that would be helpful.

Assuming these materials are at the PTO, are we correct in our understanding that you have no objection to the PTO making them available to us? If so, we would appreciate a letter to that effect. If you do object for some reason, please advise us of that. As I am sure you understand, given your assertion that MedImmune's Synagis® product is within the scope of the claims of the '415 Patent (an assertion that we will not respond to before we have completed our analysis) we have an obvious interest in the terms of the settlement agreement and the other requested documents and are unaware of any good-faith basis for your claim of confidentiality.

Finally, assuming that the '415 patent is valid, enforceable and that MedImmune would require a license under such patent for various MedImmune products under development, we note that you have not answered our question of whether Genentech would be willing to provide such licenses, other than to note that you "hope to be able to respond . . . shortly." Without conceding coverage of any particular product in development, Genentech's licensing policy with respect to the '415 patent has the potential to be a significant factor in MedImmune's research and development strategies. Thus, please advise when such a response can be expected.

Very truly yours,

/s/ William C. Bertrand, Jr.
WILLIAM C. BERTRAND, JR.
Vice President, Legal Affairs

[Exhibit 11 to Bertrand Declaration]

Genentech, Inc.

LEGAL DEPARTMENT
1 DNA Way
South San Francisco, CA 94080-4990
(650) 225-1000
FAX (650) 952-9881 or (650) 952-9882

May 16, 2002

VIA FEDERAL EXPRESS
COPY (w/o enclosure) VIA FACSIMILE (301) 527-4214
(2 PAGES)
William C. Bertrand, Jr., Esq.
Vice President, Legal Affairs
MedImmune, Inc.
35 West Watkins Mill Road
Gaithersburg, MD 20878

Re: Agreement between Genentech and MedImmune dated June 4, 1997

Dear Bill:

We write in response to your letter dated April 4, 2002 regarding our U.S. Patent No. 6,331,415.

Your letter states that you are having trouble locating the documents referred to in our letter of March 24, 2002. We filed those documents with the PTO on or about September 13, 2001, and we enclose for your reference a copy of the PTO Form 1449 that accompanied the documents when they were filed. As you will see, the Form 1449 was initialed and signed by Examiner Gambel, indicating that the documents were indeed received by the PTO and fully considered by the Examiner prior to the issuance of the '415 patent.

We trust that this additional information will allow you now to locate and to obtain copies of the documents that you are interested in and that are publicly available from the PTO. Like any member of the public, you are free to obtain copies

of publicly available documents directly from the PTO by making a request to the PTO in accordance with its rules and regulations. No letter of permission or authorization from us it required. As we believe you already are aware, however, the settlement agreement between Genentech and Celltech is not publicly available from the PTO. The settlement agreement is a confidential business document that the rules and regulations of the PTO clearly allow to be kept confidential (37 CFR 1.666(b)).

Furthermore, the settlement agreement is not relevant to the issues of the scope of claims of the '415 patent, or whether Genentech's a patent application met the requirements of U.S. law for the issuance of a patent. The PTO independently determined that Genentech's application did meet all of those requirements. We note that you have not given any explanation in either your April 4 letter or your previous correspondence as to why the settlement agreement is relevant to the question of whether or why MedImmune's Synagis® product is within the scope of the claims of the '415 patent.

Regarding MedImmune's interest in obtaining additional licenses under the '415 patent for various MedImmune products in development (identified in your February 13, 2002 letter), we are willing to meet with MedImmune representatives to discuss the availability of and terms for possible licenses for those products. If you would please let us know several dates when MedImmune representatives would be available for such a meeting, we can proceed with scheduling. We look forward to hearing from you, and to continuing our commercial relationship with MedImmune.

Very truly yours,

GENENTECH, INC.

/s/ Sean Johnston
SEAN A. JOHNSTON
Vice President, Intellectual Property

[enclosure omitted in printing]

[*Exhibit 12 to Bertrand Declaration*]

[Logo]

MedImmune, Inc.
May 23, 2002

VIA FACSIMILE: 650.952.9881

Sean A. Johnston, Esq.
Vice President, Intellectual Properly
Genentech, Inc.
Legal Department
1 DNA Way
South San Francisco, CA 94080-4990

Re: U.S. Patent No. 6,331,415 B1 ("'415 Patent")

Dear Sean:

We write in response to your letter dated May 16, 2002 with respect to the '415 Patent.

First, we are happy to meet with you to discuss whether Genentech is willing to license various MedImmune products in development on commercially reasonable terms. Specifically, we could be available to meet with you in early July (we are in the process of retaining a new head of Business Development and I would like that person to join us). I would propose a meeting any day during the week of July 8. While we do not set this as a pre-condition to any such meeting, we would again ask you to make available to MedImmune a copy of the settlement agreement that resulted in the issuance of the '415 Patent. As the Patent relates to technology that is about twenty years old, we do not understand how there could be any confidentiality issue. Moreover, contrary to your suggestion that the settlement agreement is irrelevant to the patent or our negotiations, we believe that it may very well be pertinent to our obligations, if any, with respect to the '415 Patent, given that the settlement agreement essentially forms the basis for the issuance of the patent.

Second, we appreciate your enclosing a copy of PTO Form 1449 which you say was filed with the PTO "on or about September 13, 2001." We note, however, that while the form appears to be dated by examiner Gambel on October 5, 2001, it does not indicate that it was filed "on or about September 13, 2001." We would appreciate seeing any documentation or information you could give us that would help us establish the actual filing date. Moreover, given that the settlement agreement does not appear to be included as any of the items on the Form 1449, we would also appreciate any documentation indicating when and where such agreement was filed.

We look forward to a meeting at your earliest convenience. Please let me know if we can schedule a meeting some time during the week of July 8.

Very truly yours,

/s/ William C. Bertrand, Jr.
WILLIAM C. BERTRAND, JR.
Vice President, Legal Affairs

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed Apr. 30, 2004]

Case No. CV03-2567 MRP (CTx)

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

ENTRY OF JUDGMENT

For the reasons set forth in the Amended Memorandum of Decision and Order Re Motion to Dismiss for Lack of Subject Matter Jurisdiction, this Court enters final judgment on the first, second, third and fourth causes of action and hereby dismisses those claims as to both Genentech, Inc. and City of Hope. All claims and all defendants are hereby dismissed. This Order is a final judgment for purposes of Fed. R. Civ. P. 54(a). It shall be entered pursuant to Fed. R. Civ. P. 58 and 79(a), and served upon the parties.

IT IS SO ORDERED.

DATED: April 29, 2004 /s/ Mariana R. Pfaelzer
Honorable Mariana R. Pfaelzer
United States District Judge

NON-EXCLUSIVE CABILLY PATENT LICENSE AGREEMENT

[Cabilly Coexpression Patents]

This Non-Exclusive Cabilly Patent License Agreement ("Agreement") is effective as of January 29, 2003 ("Effective Date") by and between Genentech, Inc., a Delaware corporation having its principal place of business at 1 DNA Way, South San Francisco, California 94080 (hereinafter "Genentech") and MedImmune, Inc., a Delaware corporation having its principal place of business at 35 West Watkins Mill Road, Gaithersburg, MD 20878 (hereinafter "Licensee").

WHEREAS:

A. Genentech owns and controls certain patent rights relating to methods and compositions in the field of antibodies (the "Licensed Patents", as that term is defined below);

B. Licensee is developing, and intends to commercialize, antibody products that bind to T-cell surface antigen CD2 ("CD2") and wishes to acquire a non-exclusive license for such products under the Licensed Patents; and

C. Genentech is willing to grant such a non-exclusive license to Licensee on the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the promises and the mutual covenants recited herein, the Parties agree as follows:

Article I

DEFINITIONS

Unless otherwise specifically set forth herein, the following terms shall have the following meanings:

1.01. "Affiliate" with respect to Licensee shall mean any corporation or other entity which, directly or indirectly, controls, is controlled by or is under common control with, a Party. For the purpose of this Section 1.01 "control" shall mean (i) the ownership, directly or indirectly, of at least fifty percent (50%) of the outstanding voting securities or other ownership interest of an entity, or (ii) the possession, directly or indirectly, of the power to manage, direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint fifty percent (50%) or more of the members of the governing body of the corporation or other entity.

1.02. "Bulk Product" shall mean Licensed Product supplied in a form other than Finished Product which can be converted into Finished Product.

1.03. "Calendar Quarter" shall mean each three month period commencing January 1, April 1, July 1 and October 1 of each year during the term of this Agreement.

1.04. "Chimera Patents" shall mean (i) U.S. Patent No. 4,816,567, issued March 28, 1989 from U.S. patent application serial no. (USSN) 06/483,457, and (ii) any claims specifically directed to chimeric antibodies or any method of making or using chimeric antibodies, which claims are found in any patent(s) issuing from divisionals, continuations, or continuations-in-part of any application from which U.S. Patent No. 4,816,567 claims priority, (iii) any claims specifically directed to chimeric antibodies or any method of making or using chimeric antibodies, which claims are found in any patents that are reissues, reexaminations, or extensions

of any of the foregoing (i) and (ii), and (iv) foreign counterparts of any of the foregoing (i), (ii), or (iii).

1.05. "Cost of Product" shall mean the cost of acquisition, if purchased, or the cost of manufacture, the latter being the sum of direct production costs and manufacturing overhead costs determined in accordance with U.S. Generally Accepted Accounting Principles ("GAAP").

1.06. "Designee" shall mean a corporation or other entity that is licensed by Licensee to exercise the rights of Licensee hereunder in concert with, or in place of and to the exclusion of, Licensee in all or part of the Territory on a country-by-country basis.

1.07. "Field of Use" shall mean the prevention or therapy of human disease.

1.08. "Finished Product" shall mean any and all Licensed Product in a form for use by an end user and not intended for further chemical or genetic manipulation or transformation.

1.09 "First Commercial Sale" shall mean the first sale of any Licensed Product by Licensee or any of its Affiliates or Designees to a non-affiliated third party. The sale shall be deemed to occur on the earlier of (i) the date the Licensed Product is shipped to the third party, or (ii) the date of the invoice to the third party for the Licensed Product.

1.10. "Licensed Patents" shall mean (i) U.S. Patent No. 6,331,415, issued December 18, 2001, (ii) any patent(s) issuing from divisionals, continuations, or continuations-in-part of any patent application from which U.S. Patent No. 6,331,415 claims priority, and (iii) patents that are reissues, reexaminations, extensions, or foreign counterparts of any of the foregoing (i) or (ii), provided, however, that Licensed Patents shall not include Chimera Patents.

1.11. "Licensed Product" shall mean any antibody that binds specifically to CD2, the making (or having made),

using, selling, offering for sale or importing of which, but for the license granted under this Agreement, would infringe a Valid Claim of a patent included in Licensed Patents.

[Redaction]

1.13. "Party" shall mean either Genentech or Licensee, and when used in the plural shall mean both Genentech and Licensee.

1.14. "Term" is defined in Section 7.01.

1.15. "Territory" shall mean the entire world.

1.16. "U.S." and "United States" shall mean the United States of America, including its territories and possessions.

1.17. "Valid Claim" shall mean any claim of an issued and unexpired patent within the Licensed Patents that has not been disclaimed, abandoned or dedicated to the public or held unenforceable, unpatentable or invalid by a decision of a court or governmental agency of competent jurisdiction, which decision is unappealable or unappealed within the time allowed for appeal.

Article II

GRANT

2.01. *License*. Genentech hereby grants to Licensee and Licensee hereby accepts a nonexclusive license under Licensed Patents during the Term to make (and have made), use, sell, offer for sale, and import Licensed Product in the Territory in the Field of Use. Licensee shall have a limited right to grant sublicenses as provided in Section 2.02.

2.02. *Right to Grant Sublicenses*. Licensee shall only have the right to grant sublicenses to its Affiliates and Designees of the rights granted hereunder to Licensee to make (and have made), use, sell, offer for sale, and import Licensed Product, in all or part of the Territory on a country-by-country basis; provided that Licensee shall always be responsible for the payment of royalties on Net Sales of Licensed Product by any such sublicensee and for all other acts of such sublicensee as if such acts were those of the Licensee. A sublicense granted under this Section 2.02 shall not be further sublicensable or sublicensed by the licensee thereof.

2.03. *No Other License.* Licensee understands and agrees that no license under any patent or patent application other than Licensed Patents, or under any know-how, is or shall be deemed to have been granted under this Agreement, either expressly or by implication. By way of example only, and without limitation, no license under Chimera Patents is granted hereunder.

Article III

FEES, MILESTONES AND ROYALTIES

3.01. *License Grant Fee.* Within ten (10) business days after the Effective Date, Licensee shall pay to Genentech a non-creditable, non-refundable license grant fee of . . . dollars (U.S. $ . . .).

3.02. *Development Milestone Fee.* Within ten (10) business days after receipt by Licensee of the first marketing approval for a Licensed Product from the United States Food and Drug Administration or any successor agency or authority thereto ("FDA"), Licensee shall pay to Genentech a non-creditable, non-refundable development milestone fee of $ . . . dollars (U.S. $ . . .).

3.03. *Earned Royalties.* . . . .

3.04. *Sales To or Between Licensee, Affiliates, and Designees.* . . . .

3.05. *No Non-Monetary Consideration.* . . . .

3.06. *No Credit Against Royalties.* . . . .

Article IV

RECORDS, REPORTS AND PAYMENTS

4.01. *Records Retention.* Licensee shall keep and shall cause its Affiliates and Designees to keep true, complete and accurate records of all sales of all Licensed Product in accordance with GAAP, or the equivalent, and in sufficient detail to permit Genentech to confirm the accuracy of Licensee's royalty calculations. At Genentech's request and expense, Licensee shall permit not more than once in a twelve (12) month period an independent certified public accountant appointed by Genentech and acceptable to Licensee to examine at Licensee's principal place of business, upon reasonable notice and at reasonable times, such records solely to the extent necessary to verify Licensee's calculations. Licensee shall be responsible for providing access to such records that in the ordinary course of business are in the possession or control of its Affiliates and Designees. Such examination shall be limited to a period of time no more than three (3) years immediately preceding the request for examination. The report of any such examination shall be made simultaneously to Genentech and Licensee and shall simply report the amount, if any, by which Licensee has overpaid or underpaid its royalties. If Licensee's royalties are found to be in error such that royalties to Genentech were underpaid, then Licensee shall promptly pay the deficiency

plus interest pursuant to Section 4.05 to Genentech; and if royalties to Genentech were underpaid by more than five percent (5.0%), then Licensee shall additionally reimburse Genentech for its reasonable costs incurred in examining such records.

4.02. *Reports*. Within sixty (60) days after the end of each Calendar Quarter following the First Commercial Sale of Licensed Product, Licensee shall furnish to Genentech a written report of all sales of all Licensed Product subject to royalty under Article III during such Calendar Quarter. Such report shall include, without limitation, (i) the determination of Net Sales as specified in Section 1.12, setting forth the amount of gross receipts, Net Sales, and any deduction taken from gross receipts to arrive at Net Sales, for each of Finished Product and Bulk Product separately; and (ii) the royalty payment then due. Concurrently with each report pursuant to this Section 4.02, Licensee shall make the royalty payment then due.

4.03. *Payments*. Payments shall be in United States dollars and, unless otherwise agreed in writing, shall be made by wire transfer of immediately available funds to such account of Genentech in such bank as Genentech may from time to time designate in writing. All royalty payments shall be free and clear of any taxes, duties, levies, fees or charges, except for withholding taxes. Licensee shall pay any withholding tax due on behalf Genentech and such withholding taxes shall be deducted from all payments due hereunder. The Parties shall cooperate to take advantage of the benefit of any double taxation treaty(ies) that may be applicable.

4.04. *Currency Conversion*. Royalties due on Net Sales of Licensed Product made in currency other than U.S. dollars shall be expressed in the currency of the invoice issued in connection with the sale of such Licensed Product together with the U.S. dollar equivalent of the royalty due, calculated

using the average rate of exchange published in Reuters during the applicable Calendar Quarter.

4.05. *Interest.* All royalty payments not made when due shall bear interest, calculated from the date such payment was due, at the annual rate of two percent (2%) over the prime rate of interest as reported in the *Wall Street Journal* on the day the payment was due.

Article V

REPRESENTATIONS, WARRANTIES, AND DISCLAIMERS

5.01. Genentech represents and warrants that it has the right to grant the license granted under this Agreement.

5.02. Nothing in this Agreement is or shall be construed as:

(i) A warranty or representation by Genentech as to the validity or scope of any claim or patent or patent application within the Licensed Patents;

(ii) A warranty or representation by Genentech that anything made, used, sold, or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of any patent rights or other intellectual property right of any third party;

(iii) A grant by Genentech, whether by implication, estoppel, or otherwise, of any licenses or rights other than that expressly granted under Section 2.01; or

(iv) An obligation to bring or prosecute actions or suits against any third party for infringement of any of the Licensed Patents.

5.03. NO WARRANTY IS GIVEN WITH RESPECT TO THE LICENSED PATENTS, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND THE PARTIES SPECIFICALLY DISCLAIM ANY EXPRESS OR IMPLIED WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF THE LICENSED PATENTS, OR NON-INFRINGEMENT OF THE PATENT OR OTHER RIGHTS OF ANY THIRD PARTY.

Article VI

LIABILITY

6.01. *Indemnification.* Licensee shall indemnify, defend and hold Genentech and its directors, officers, employees and agents harmless from and against any and all liabilities, claims, demands, expenses (including, without limitation, attorneys and professional fees and other costs of litigation), losses or causes of action in each of the foregoing cases of, by, for or to a third party (each, a "Liability") arising out of or relating in any way to (i) the possession, manufacture, use, sale or other disposition of Licensed Product by Licensee or its Affiliates or Designee hereunder, whether based on breach of warranty, negligence, product liability or otherwise, (ii) the exercise of any right granted to Licensee pursuant to this Agreement, or (iii) any breach of this Agreement by Licensee, except to the extent, in each case, that such Liability is caused by the gross negligence or willful misconduct of Genentech as determined by a court of competent jurisdiction; provided, however, that upon receiving notice of any such Liability, Genentech shall promptly notify Licensee and permit Licensee to handle and control the defense (including litigation and settlement) of such Liability, at Licensee's sole expense, and Genentech shall reasonably cooperate with the indemnifying Party in the defense of such Liability, at Licensee's sole expense. The indemnification of this Section 6.01 shall not apply to any settlement, compromise or ad-

mission of liability made by a person or entity to be indemnified hereunder without the written consent of Licensee.

Article VII

TERM AND TERMINATION

7.01. *Term*. The term of this Agreement will commence on the Effective Date and remain in full force and effect until the expiration of the last patent within the Licensed Patents (the "Term"), unless earlier terminated in accordance with this Article VII.

7.02 *Termination without Breach*. Licensee shall have the right to terminate this Agreement upon ninety (90) days prior written notice to Genentech.

7.03. *Termination for Breach*. Genentech shall have the right to terminate this Agreement and the licenses granted hereunder upon written notice to Licensee for a material breach of this Agreement if Licensee has failed to cure such breach within thirty (30) days following notice thereof. Licensee's failure to pay royalties and provide reports to Genentech under this Agreement when due shall constitute a material breach.

7.04. *Insolvency*. Genentech may terminate this Agreement if, at any time, Licensee shall file in any court pursuant to any statute of any individual state or country, a petition in bankruptcy, insolvency or for reorganization or for an agreement among creditors or for the appointment of a receiver or trustee of Licensee or of its assets, or if Licensee proposes a written agreement of composition or extension of its debts, or if Licensee shall be served with an involuntary petition against it filed in any insolvency proceeding, and such petition shall not be dismissed within sixty (60) days after the filing thereof, or if Licensee shall propose or be a party to any dissolution or liquidation, or if Licensee shall make an

assignment for the benefit of creditors. Any termination pursuant to this Section 7.04 shall be effective immediately upon notice of such termination.

7.05. *Effect of Termination.* Termination of this Agreement in whole or in part for any reason shall not relieve Licensee of its obligations to pay all fees and royalties that shall have accrued hereunder prior to the effective date of termination. Termination of this Agreement by or as to Licensee shall result in the termination of the licenses granted to Licensee and to all sublicensees of Licensee pursuant to this Agreement. The provisions of Article IV, Article V, Article VI, Article VIII and this Section 7.05 shall survive termination of the Agreement for any reason.

Article VIII

MISCELLANEOUS PROVISIONS

8.01. *Relationship of the Parties.* Nothing in this Agreement is intended or shall be deemed to constitute or give rise to a partnership, agency, distributorship, employer-employee, joint venture, or fiduciary relationship between the Parties. No Party shall incur any debts or make any commitments for the other.

8.02. *Patent Prosecution, Maintenance and Enforcement.* Genentech shall be solely responsible, at its sole discretion and expense, for the prosecution, defense, and maintenance of Licensed Patents, and for enforcing Licensed Patents against actual or suspected third party infringers.

8.03. *Assignment.* (a) Neither Party shall assign any of its rights or obligations hereunder except: (i) as incident to the merger, consolidation, reorganization or acquisition of stock or assets affecting substantially all of the assets or voting control of the assigning Party; (ii) to any corporation or other entity to which it may transfer substantially all of its assets related to the Licensed Product; (iii) to any wholly owned

subsidiary if the assigning Party remains liable and responsible for the performance and observance of all of the subsidiary's duties and obligations hereunder; or (iv) with the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided however, that assignment in the context of insolvency or bankruptcy of Licensee shall require prior written consent of Genentech. This Agreement shall be binding upon the successors and permitted assigns of the Parties, and the name of a Party appearing herein shall be deemed to include the names of such Party's successor's and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 8.03 shall be void.

(b) Any assignment or transfer of rights by Genentech (in whole or in part) in or to Licensed Patents to any third party shall be subject to the grant of rights to Licensee herein.

8.04. *Further Acts and Instruments*. Upon request by either Party, the other Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

8.05. *Trade Names and Trademarks*. Except as otherwise provided herein, no right, expressed or implied, is granted by this Agreement to use in any manner the name "Genentech" or any other trade name or trademark of Genentech in connection with the performance of this Agreement. Except as otherwise provided herein, no right, expressed or implied, is granted by this Agreement to use in any manner the name "MedImmune" or any other trade name or trademark of Licensee in connection with the performance of this Agreement.

8.06. *Entire Agreement*. This Agreement constitutes and contains the entire understanding and agreement of the Parties with respect to the subject matter hereof, and cancels and

supersedes any and all prior negotiations, correspondence, understandings and agreements, whether verbal or written, between the Parties respecting the subject matter hereof. No waiver, modification, or amendment of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized representative of each of the Parties.

8.07. *Severability*. In the event any one or more of the provisions of this Agreement should for any reason be held by any court or authority having jurisdiction over this Agreement or either of the Parties to be invalid, illegal or unenforceable, such provision or provisions shall be validly reformed to as nearly as possible approximate the intent of the Parties and, if unreformable, shall be divisible and deleted in such jurisdiction; elsewhere, this Agreement shall not be affected so long as the Parties are still able to realize the principal benefits bargained for in this Agreement.

8.08. *Waiver*. The waiver by a Party of any breach of or default under any of the provisions of this Agreement or the failure of a Party to enforce any of the provisions of this Agreement or to exercise any right hereunder shall not constitute or be construed as a waiver of any other breach or default or as a waiver of any such rights or provisions hereunder.

8.09. *Choice of Law*. This Agreement shall be governed by and interpreted in accordance with the laws of the State of California without regard to conflict of laws provisions. This Agreement shall be construed as if drafted equally by the Parties, and in construing this Agreement no presumption shall operate in either Party's favor as a result of the role of it or its counsel in drafting or negotiating the terms or provisions hereof.

8.10. *Notices*. Any notice, request, consent, or other document required or permitted to be given under this Agreement or otherwise relating to this Agreement shall be in writing and

shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (with a confirming copy sent by overnight courier), or sent by overnight courier or registered mail to the Party to whom it is directed at its address shown below or such other address as such Party shall have last given by notice to the other Party. Any such notice, requests, delivery, approval or consent shall be deemed received on the date of hand delivery or transmission by facsimile (provided that such date is a business day, otherwise it shall be deemed received on the next business day), one (1) business day after dispatch by overnight courier, or five (5) business days after dispatch of the registered mail.

If to Licensee, addressed to:

MedImmune, Inc.
35 West Watkins Mill Road
Gaithersburg, MD 20878
Attn: Manager, Business Development

Facsimile: (301) 527-4214

If to Genentech, addressed to:

Genentech, Inc.
1 DNA Way
South San Francisco, CA 94080
Attn: Corporate Secretary

Facsimile: (650) 952-9881

8.11. *Confidentiality*. (a) Each Party shall be free to disclose the existence of this Agreement (but not its terms) to any third party. Neither Party shall disclose any of the terms (including, but not limited to, the financial terms) of this Agreement to any third party without the prior written consent of the other Party; provided, however, that each Party shall be free to disclose any of the terms of this Agreement (i) to the extent that a Party reasonably believes it is required to do so by securities or other applicable laws, regulations, or

rules (including the regulations or rules of any relevant stock exchange), (ii) pursuant to a legal proceeding or order of a court or governmental agency, (iii) to actual or prospective sublicensees, (iv) to City of Hope National Medical Center (in the case of Genentech), (v) to its accountants, attorneys and other professional advisors, or (vi) in connection with a financing, merger, consolidation, acquisition or a permitted assignment of this Agreement, provided that in the case of any disclosure under (iii), (iv), (v), or (vi) above, the recipient(s) are obligated and do so undertake to keep such terms of this Agreement confidential to the same extent as said Party, and provided that in the case of disclosure under (ii), the disclosing Party will use reasonable efforts to secure confidential treatment of such terms of this Agreement required to be disclosed.

(b) Genentech shall not disclose the content of reports of Section 4.02 and/or reports received under Section 4.01 other than to its accountants, attorneys and other professional advisors who are obligated to similar non-disclosure obligations, provided, however, that Genentech shall be free to disclose the content of reports of Section 4.02 and/or reports received under Section 4.01 (i) to the extent that Genentech reasonably believes it is required to do so by securities or other applicable laws, regulations, or rules (including the regulations or rules of any relevant stock exchange), (ii) pursuant to a legal proceeding or order of a court or governmental agency, (iii) to actual or prospective sublicensees, (iv) to City of Hope National Medical Center, (v) to its accountants, attorneys and other professional advisors, or (vi) in connection with a financing, merger, consolidation, acquisition or a permitted assignment of this Agreement, provided that in the case of any disclosure under (iii), (iv), (v), or (vi) above, recipient(s) are obligated and does so undertake to keep such content of reports of Section 4.02 and/or reports received under Section 4.01 confidential to the same extent as Genentech, and provided that in the case of

disclosure under (ii), Genentech will use reasonable efforts to secure confidential treatment of such content of reports of Section 4.02 and/or reports received under Section 4.01 required to be disclosed.

8.12. *Counterparts*. This Agreement may be executed simultaneously in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

8.13 *Bankruptcy*. All rights and licenses granted under or pursuant to this Agreement by Genentech to Licensee are, and shall irrevocably be deemed to be, "intellectual property" as defined in Section 101(56) of the U.S. Bankruptcy Code. In the event of the commencement of a case by or against either party under any Chapter of the above mentioned Bankruptcy Code, this Agreement shall be deemed an executory contract and all rights and obligations hereunder shall be determined in accordance with Section 365 of the above mentioned Bankruptcy Code, including, without limitation, Section 365(n) thereof.

IN WITNESS WHEREOF, Genentech and Licensee have caused this Agreement to be executed by their duly authorized representatives.

GENENTECH, INC.

By: Sean Johnston
Sean A. Johnston, Ph.D.
Title: Vice President, Intellectual Property

Date: January 28, 2003

MEDIMMUNE, INC.

By: David M. Mott
David M. Mott
Chief Executive Officer and Vice Chairman

Date: February 17, 2003

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

[Filed May 5, 2004]

Case No. CV03-2567 MRP (CTx)
Hon. Mariana R. Pfaelzer

MEDIMMUNE, INC.,

Plaintiff,

vs.

GENENTECH, INC., CITY OF HOPE, and CELLTECH R&D LTD.,

Defendants.

NOTICE OF APPEAL

Notice is hereby given that Plaintiff MedImmune, Inc. in the above named case hereby appeals to the United States Court of Appeals for the Federal Circuit from a Final Judgment dismissing MedImmune's First, Second, Third and Fourth causes of action as to both Genentech, Inc. and City of Hope, entered on April 30, 2004 (a copy of which is attached as Exhibit A). All claims as to all defendants in the above named action have now been dismissed.

Dated: May 5, 2004

DEWEY BALLANTINE LLP
By: /s/ Jeffrey R. Witham
JEFFREY R. WITHAM
Attorneys for Plaintiff
MEDIMMUNE, INC.

[Exhibit omitted in printing]

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

04-1300, -1384

MEDIMMUNE, INC.,
Plaintiff-Appellant,

v.

GENENTECH, INC.,
Defendant-Appellee,

and

CITY OF HOPE,
Defendant-Appellee,

and

CELLTECH, R&D, LTD.,
Defendant-Appellee.

JUDGMENT

ON APPEAL from the United States District Court for the Central District of California

In CASE NO(S). 03-CV-2567

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED: AFFIRMED

DATE: OCT. 18, 2005

ENTERED BY ORDER OF THE COURT
Vanxorbaly, Clerk

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

MEDIMMUNE V GENENTECH, 04-1300
DCT - 03-CV-2567

NOTICE OF ENTRY OF
JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED:
10/18/05

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and petitions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

Costs are taxed against the Appellant(s) under Rule 39. The party entitled to costs is provided a bill of costs form and an instruction sheet with this notice.

The parties are encouraged to stipulate to the costs. A bill of costs will be presumed correct in the absence of a timely filed objection.

Costs are payable to the party awarded costs. If costs are awarded to the government, they should be paid to the Treasurer of the United States. Where costs are awarded against the government, payment should be made to the person(s) designated under the governing statutes, the court's orders, and the parties' written settlement agreements. In cases between private parties, payment should be made to counsel for the party awarded costs or, if the party is not represented by counsel, to the party pro se. Payment of costs should not be sent to the court. Costs should be paid promptly.

If the court also imposed monetary sanctions, they are payable to the opposing party unless the court's opinion provides otherwise. Sanctions should be paid in the same way as costs.

Regarding exhibits and visual aids: Your attention is directed to FRAP 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.

JAN HORBALY
Clerk

cc: HARVEY KURZWEIL
D. WALL, J. LIPNER, C. BARQUIST

SUPREME COURT OF THE UNITED STATES

No. 05-608

MEDIMMUNE, INC.,

Petitioner,

v.

GENENTECH, INC., et al.

ON PETITION FOR A WRIT OF CERTIORARI to the United States Court of Appeals for the Federal Circuit, No. 04-1300, 04-1384.

ON CONSIDERATION of the petition for a writ of certiorari herein to the United States Court of Appeals for the Federal Circuit.

IT IS ORDERED by this Court that the said petition is granted.

February 21, 2006